

01/26/99  
C625 U.S. PTO



APPLICATION

EXHIBIT A  
PAGE 1 OF 5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. HERO113397

TRANSMITTAL LETTER

Seattle, Washington 98101

January 26, 1999

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Transmitted herewith for filing under 37 C.F.R. § 1.53(b) by Express Mail is the

- X   a. complete  
       b. incomplete

patent application of: Stephen J. Brown,

Title: MODULAR MICROPROCESSOR-BASED HEALTH MONITORING SYSTEM

- X   1. This application is a continuation of prior application No. 08/481,925, filed June 7, 1995, which is a continuation of prior application No. 08/233,397, filed April 26, 1994, now abandoned, which is a continuation-in-part of prior application No. 07/977,323, filed November 17, 1992 now U.S. Patent No. 5,307,263, priority from the filing date of which is hereby claimed under 35 U.S.C. § 120.
- X   2. An application consisting of 35 pages of specification and claims and 6 sheets of formal drawings is attached.
- X   3. A copy of the Declaration and Power of Attorney filed in the above noted prior application is attached.
- X   i. The entire disclosure of the prior application, from which a copy of the declaration is supplied, is considered as being part of the disclosure of this application and is hereby incorporated by reference herein.

LAW OFFICES OF  
CHRISTENSEN O'CONNOR JOHNSON & KINDNESS<sup>LLC</sup>  
1420 Fifth Avenue  
Suite 2800  
Seattle, Washington 98101  
(206) 682-8100

01/26/99  
09/23/94  
JL:542 U.S. PTO

09237194-012699

- X 4. The prior application was assigned to Raya Systems, Inc., by an assignment recorded at reel 6976/frame 0623, a copy of which is attached. Raya Systems, Inc. has changed its name to Health Hero Network, Inc.
- X 5. A copy of the Certificate of Change of Name to Health Hero Network, Inc. is attached.
- X 6. A filing date in accordance with 37 C.F.R. § 1.10 is requested. The Express Mail Certificate appears below.
- X 7. A Small Entity Statement was filed in the prior application. Small entity status is still proper and desired in this application.
- X 7a. A Preliminary Amendment will be filed within the next three months.

COMPUTATION OF FEE

	Number Filed		Number Extra		Rate		Basic Rate \$380.00
Total Claims	19 - 20	=	0	x	\$9	=	\$0.00
Independent Claims	2 - 3	=	0	x	\$39	=	\$0.00
Multiple Dependent Claims	0		---		\$130	=	\$0.00
TOTAL							\$380.00

- X 8. Our check No. 102820 in the amount of \$380.00 to cover the total fee as computed above is enclosed.
- X 9. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.18 which may be required during the entire pendency of the application, or credit any overpayment, to Deposit Account No. 03-1740. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire prosecution of this application. A copy of this sheet is enclosed.

LAW OFFICES OF  
CHRISTENSEN O'CONNOR JOHNSON & KINDNESS<sup>LLC</sup>  
1420 Fifth Avenue  
Suite 2800  
Seattle, Washington 98101  
(206) 682-8100

Please address all further correspondence to:

CHRISTENSEN O'CONNOR JOHNSON & KINDNESS<sup>PLLC</sup>  
1420 Fifth Avenue  
Suite 2800  
Seattle, WA 98101

Respectfully submitted,

CHRISTENSEN O'CONNOR  
JOHNSON & KINDNESS<sup>PLLC</sup>

*Richard T. Black*

Richard T. Black  
Registration No. 40,514  
Direct Dial (206) 695-1724

EXPRESS MAIL CERTIFICATE

"Express Mail" mailing label number EM605200668US

Date of Deposit January 26, 1999

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Scott Michaelis

(Typed or printed name of person mailing paper or fee)

*Scott Michaelis*

(Signature of person mailing paper or fee)

RTB:kh

LAW OFFICES OF  
CHRISTENSEN O'CONNOR JOHNSON & KINDNESS<sup>PLLC</sup>  
1420 Fifth Avenue  
Suite 2800  
Seattle, Washington 98101  
(206) 682-8100

09237194-012699



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**Supplemental Application Data Sheet**

**Application Information**

Application number:: 09/237194  
Filing Date:: 01/26/99  
Application Type:: Regular  
Subject Matter:: Utility  
Suggested Group Art Unit:: 3626  
CD-ROM or CD-R?: None  
Sequence submission?: None  
Computer Readable Form (CRF)?:: No  
Title:: MODULAR MICROPROCESSOR-BASED  
HEALTH MONITORING SYSTEM  
Attorney Docket Number:: 014030.0110N2US  
Request for Early Publication?: No  
Request for Non-Publication?: No  
Small Entity?: No  
Petition included?: No  
Secrecy Order in Parent Appl.?: No

**Applicant Information**

Applicant Authority Type:: Inventor  
Status:: Full Capacity  
Given Name:: Stephen  
Middle Name:: James  
Family Name:: Brown  
Street of mailing address:: 2570 West El Camino Real  
Suite 111  
City of mailing address:: Mountain View  
State or Province of mailing address:: CA  
Postal or Zip Code of mailing address:: 94040

**Correspondence Information**

BEST AVAILABLE COPY



Correspondence Customer Number:: 32042

**Representative Information**

Representative Customer Number:: 32042

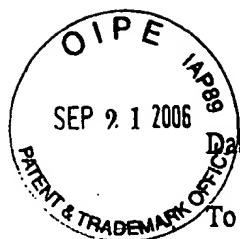
**Domestic Priority Information**

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
09/237,194	Continuation of	08/481,925	06/07/95
<u>08/481,925</u>	<u>Continuation of</u>	<u>08/233,397</u>	<u>04/26/94</u>
<u>08/233,397</u>	<u>Continuation-in-part</u> <u>of</u>	<u>07/977,323</u>	<u>11/17/92</u>

**Foreign Priority Information**

**Assignee Information**

Assignee name:: Health Hero Network, Inc.  
Street of mailing address:: 2570 West El Camino Real  
Suite 111  
City of mailing address:: Mountain View  
State or Province of mailing address:: CA  
Postal or Zip Code of mailing address:: 94040



Date March 2, 1992

To ✓ Dr. Norbert Jersch  
✓ Dr. Thomas Keiser  
Central Marketing Patient Systems  
Boehringer Mannheim GmbH  
fax (011 49 621) 759 4179

From Steve Brown  
Raya Systems  
Mountain View, CA  
fax (415) 949 3935

re Camit, Diabcare

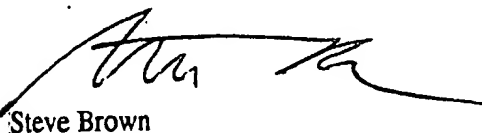
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Thank you for the order for Camit 2.5. We accept the conditions, except that we would like to start development on April 6, rather than March 1. As I discussed with Hartmut, it makes more sense for us start closer to the time when a prototype will be available. I want to devote continuous attention to the project until completion, rather than doing some development now and then waiting for the prototype EL.

With regard to Diabcare, I would like to have a new agreement confirming our fax transmittals of the last two months.

I have developed an interface for the Camit EL to a Nintendo video game machine, and am producing a data management program for the Super Nintendo Entertainment System. In the United States, Nintendo video game computers are in 40 million homes. They are inexpensive and attach to television sets. Raya Systems is licensed by Nintendo to produce such a product, and I hope to discuss the possibilities with BM USA. Can you tell me who to contact there? This could be an ideal platform for a home system which connects to the doctor system (Camit) via modem.

Sincerely,



Steve Brown



March 5, 1992

Reference: 1 R43 DK44402-01

Dr. Charles Wells  
Director, Diabetes Research Program  
National Institute of Diabetes and Digestive and Kidney Diseases  
Division of Diabetes, Endocrinology and Metabolic Diseases  
National Institutes of Health, Westwood Building Room 622  
5333 Westbard Avenue  
Bethesda, MD 20892

Dear Dr. Wells:

We are just finishing our Phase I SBIR project, "Computer Game For Diabetes Education," and we are preparing to apply for Phase II before the April 15 closing date. In Phase I, we modified and evaluated a prototype game we had developed, and designed a Nintendo game which we intended to develop and study in Phase II. In Phase III, we hoped to commercialize the game by working with a corporate sponsor.

As I mentioned on the phone, I have found a corporate sponsor to fund the development and production of a first version of a Nintendo game based on our design and results from Phase I. Although it seems that we have already made it to Phase III with only Phase I funding, important research remains to be done, and I hope to apply for Phase II funding.

I would like to do a longer term controlled study with the educational Nintendo game in patients' homes. We will develop the game cartridges to record some measures internally, give the game cartridges to patients, and then collect them two months later to determine which aspects of our design were the most effective. We will test subjects before and after the two month period and compare results to a control group who received a Nintendo game unrelated to diabetes. A longer term study also allows us to use clinical measures such as glycosylated hemoglobin.

We have already demonstrated that a video game is a feasible approach for diabetes education. It only remains to focus the game on its strongest points, and then develop a full blown, entertainment quality Nintendo game which could be an important teaching and motivational tool for children with diabetes.

My question to you is: Given our situation, is it still appropriate for us to apply for Phase II funding? Important research remains to be done, and will not occur without this funding. We have, however, already begun to commercialize the product. I understand that developing a commercial product is the intent of the SBIR program, but it is not clear to me at which phase this process may begin. I believe we are now in a better position to do a more powerful study, and that an NIDDK grant can be used more efficiently to evaluate and further develop the educational aspects of a Nintendo game designed to teach children about diabetes, because a corporate sponsor has already covered some of the costs of developing such a game.

Sincerely,

Steve Brown  
President  
Raya Systems, Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE  SMALL BUSINESS INNOVATION RESEARCH PROGRAM PHASE I GRANT APPLICATION  FOLLOW INSTRUCTIONS CAREFULLY		LEAVE BLANK		
		TYPE	ACTIVITY	NUMBER
		REVIEW GROUP		FORMERLY
		COUNCIL/BOARD (Month/year)		DATE RECEIVED
1. TITLE OF APPLICATION (Do not exceed 56 typewriter spaces) Computer Game for Diabetes Education				
2. SBIR SOLICITATION NO. PHS 90-2				
3. PRINCIPAL INVESTIGATOR				<input checked="" type="checkbox"/> New Investigator
3a. NAME (Last, first, middle) Brown, Stephen James				3b. SOCIAL SECURITY NO. 539-66-5116
3c. POSITION TITLE President Raya Systems, Incorporated		3d. MAILING ADDRESS (Street, city, state, zip code) 2570 West El Camino Real Suite 309 Mountain View, California 94040		
3e. TELEPHONE (Area code, number and extension) (415) 949-3933				
4. HUMAN SUBJECTS <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES { <input checked="" type="checkbox"/> Exemption # 1, 2, 3 OR <input type="checkbox"/> Form HHS 596 enclosed		5. VERTEBRATE ANIMALS <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES		
6. DATES OF PROJECT PERIOD From: 7/1/91 Through: 12/31/91		7. COSTS REQUESTED 7a. Direct Costs \$ 41,200 7b. Total Costs \$ 49,200		
8. PERFORMANCE SITES (Organizations and addresses)  Stanford University Medical Center Department of Pediatrics Stanford, California 94305  Raya Systems, Incorporated 2570 West El Camino Real Suite 309 Mountain View, California 94040		9. APPLICANT ORGANIZATION (Name, address, and congressional district) Raya Systems, Incorporated 2570 West El Camino Real Suite 309 Mountain View, California 94040 12th Congressional District		
		10. ENTITY IDENTIFICATION NUMBER 77-0207109		
		11. SMALL BUSINESS CERTIFICATION <input checked="" type="checkbox"/> Small business <input type="checkbox"/> Minority and disadvantaged <input type="checkbox"/> Woman-owned		
12. NOTICE OF PROPRIETARY INFORMATION The information identified by asterisks (*) on pages _____ of this application constitutes trade secrets or information that is commercial or financial and confidential or privileged. It is furnished to the Government in confidence with the understanding that such information shall be used or disclosed only for evaluation of this application; provided that, if a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information herein to the extent provided by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.				
13. DISCLOSURE PERMISSION STATEMENT If this application does not result in an award, is the Government permitted to disclose the title only of your proposed project, and the name, address and telephone number of the corporate official of your firm, to organizations that may be interested in contacting you for further information or possible investment? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO		14. CORPORATE OFFICIAL (Name, title, address and telephone number) Stephen J. Brown President, Raya Systems, Inc. 2570 W El Camino Real, Ste 309 Mountain View, CA 94040 (415) 949-3933		
15. PRINCIPAL INVESTIGATOR ASSURANCE: I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application. Willful provision of false information is a criminal offense (U.S. Code, Title 18, Section 1001).		SIGNATURE OF PERSON NAMED IN 3a (In ink. "Per" signature not acceptable)		DATE 12/14/90
16. CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true and complete to the best of my knowledge, and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as the result of this application. A willfully false certification is a criminal offense (U.S. Code, Title 18, Section 1001).		SIGNATURE OF PERSON NAMED IN 14. (In ink. "Per" signature not acceptable)		DATE 12/14/90

## ABSTRACT OF RESEARCH PLAN

EXHIBIT C

PAGE 4 OF 11

NAME, ADDRESS AND TELEPHONE NUMBER OF APPLICANT ORGANIZATION

Raya Systems, Incorporated  
2570 West El Camino Real, Suite 309  
Mountain View, California 94040  
(415) 949-3933

YEAR FIRM FOUNDED 1988

NO. OF EMPLOYEES (include all affiliates)

seven

TITLE OF APPLICATION

Computer Game for Diabetes Education

KEY PROFESSIONAL PERSONNEL ENGAGED ON PROJECT

NAME	POSITION TITLE	ORGANIZATION
Stephen J. Brown	President and	Raya Systems, Inc.
Dr. Mark Lepper	Principal Investigator	Stanford University
Dr. Raymond Hintz	Professor and Chairman, Department of Psychology	Stanford University
	Professor and Head, Pediatric Endocrinology	Medical Center

**ABSTRACT OF RESEARCH PLAN:** State the application's long-term objectives and specific aims, making reference to the health-relatedness of the project, describe concisely the methodology for achieving these goals, and discuss the potential of the research for technological innovation and commercial application. Avoid summaries of past accomplishments and the use of the first person.

The abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. Since abstracts of funded applications may be published by the Federal Government, do not include proprietary information. DO NOT EXCEED 200 WORDS.

This proposal seeks support for the development and evaluation of an educational computer game for children with diabetes. The goal is to impart essential knowledge and encourage positive attitudes and behaviors. Diabetes is managed largely by patients themselves; patient knowledge and attitude are critical to the success of any treatment. Raya Systems has created a prototype role-playing computer game to address these needs. In the formative phase of this study, experts in education and pediatric endocrinology will evaluate this prototype, and children at a pediatric diabetes ward will play it. The prototype will be modified on the basis of this evaluation. In the summative phase, the impact on in-patient diabetes education will be studied. On alternating months over a four month period, the game will be used at pediatric diabetes education sessions. Children, parents and physicians will be surveyed, and the impact on children's knowledge, attitudes, communication and cooperation with peers will be observed. The final report will assess the game's effectiveness for diabetes education, and will recommend a design for a Nintendo<sup>R</sup> game. Raya Systems is a licensed Nintendo<sup>R</sup> developer, and in Phase II, the Nintendo<sup>R</sup> game will be programmed. The final product will be marketed to pediatricians and parents with diabetic children.

Provide key words (8 maximum) to identify the research or technology.

Computer Game for Diabetes Education

Provide a brief summary of the potential commercial applications of the research.

The research will result in a marketable video game to aid in education of children with diabetes which can be sold to parents, teachers, and physicians.

PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR: Stephen J. Brown

BUDGET FOR PHASE I DIRECT COSTS ONLY					FROM 7/1/91	THROUGH 12/31/91	DOLLAR AMOUNT REQUESTED (Omit ce	
PERSONNEL (Applicant organization only)		1 TYPE EMPL.	2 % OF EMPL.	3 EFFORT ON PROJ.	SALARY	FRINGE BENEFITS	TOTAL	
NAME	ROLE IN PROJECT							
Stephen J. Brown	Principal Investigator	1.0	50	0.5	36,000		18,000	
Aaron Davis	Programmer	1.0	20	0.2	36,000		7,200	
James Wehner	Writer/Artist	1.0	20	0.2	36,000		7,200	
SUBTOTALS								
CONSULTANT COSTS		Raymond L. Hintz, M.D., Stanford University Mark R. Lepper, Ph.D., Stanford University					3,000 3,000	
EQUIPMENT (Itemize)		IBM PC compatible computer with VGA graphics					3,000	
SUPPLIES (Itemize by category)		Computer supplies					200	
TRAVEL		DOMESTIC FOREIGN						
PATIENT CARE COSTS		INPATIENT OUTPATIENT						
CONTRACTUAL COSTS								
OTHER EXPENSES (Itemize by category)								
		+ 50%						
TOTAL DIRECT COSTS (Also enter on page 1, item 7a)							\$ 41,200	
▶ This figure, when added to the indirect costs, normally may not exceed \$50,000.								

OTHER GRANT AND  
CONTRACT SUPPORT  
(see instructions)☒ NO ☐ YES

---

**BUDGET JUSTIFICATION**

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Using continuation pages if necessary, describe the specific functions of the personnel and consultants. Read the instructions and justify all costs requested.

EXHIBIT C  
PAGE 6 OF 11

**Personnel**

Steve Brown will manage the study, direct the focus-group and testing sessions, and draft the final report. Aaron Davis will code revisions to the software between the formative and summative phases. James Wehner will draft and illustrate questionnaires, provide computer art for game revisions, and help produce the final report.

**Consultants**

Dr. Raymond Hintz will supervise the medical content of the software. Dr. Lepper will provide educational and experimental expertise and guidance.

**Equipment**

One IBM PC or compatible computer with VGA graphics is requested for testing at the Stanford University Pediatric Endocrinology Ward's classrooms.

**Supplies**

Computer supplies are needed for the programming and testing components of the research.

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**RESOURCES AND ENVIRONMENT**

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1. **FACILITIES:** Describe the facilities to be used and briefly indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Include laboratory, clinical, animal, computer, and office facilities at the applicant organization, at any other performance site listed on the FACE PAGE, and at sites for field studies. Using continuation pages if necessary, include an explanation of any consortium arrangements with other organizations.

Raya Systems employs 7 persons, and has a third floor office of approximately 3,000 square feet. Secure storage, telephones and a conference room will be available. The Stanford University Pediatric Endocrinology Ward will provide classrooms for use in the study.

2. **MAJOR EQUIPMENT:** List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

One IBM PC computer will be made available at the Raya Systems office for coding and revision of the prototype.

3. **ADDITIONAL INFORMATION:** Provide any other information describing the environment for the project. Identify support services such as consultants, secretarial, machine shop, and electronics shop, and the extent to which they will be available to the project. Photocopying and other office services are near to Raya Systems' offices.



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE

NOTICE OF GRANT AWARD

DATE ISSUED: 09/05/91  
GRANT NUMBER: HUD-3 (AHR-B)  
1 R43 DK44402-01

TITLE OF AWARD: SMALL BUSINESS INNOVATION RESEARCH PROG  
AUTHORIZED BY: 42 USC 241 42 CFR PART 52 15 USC 638

TOTAL PROJECT PERIOD:  
From 09/05/91 Through 03/05/92

AWARDED BY: NAT INST OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Title of Project or Area of Training

COMPUTER GAME FOR DIABETES EDUCATION

Grantee Organization  
RAYA SYSTEMS INCORPORATED  
2570 WEST EL CAMINO REAL  
SUITE 309  
MOUNTAIN VIEW, CA 94040

Principal Investigator/Program Director/Awardee  
BROWN, STEPHEN J  
RAYA SYSTEMS INCORPORATED  
2570 WEST EL CAMINO REAL  
SUITE 309  
MOUNTAIN VIEW, CA 94040 12

APPROVED BUDGET  
FOR BUDGET PERIOD 09/05/91 Through 03/05/92  
Salaries and Wages .....\$ 32,400  
Fringe Benefits ..... 32,400  
Total Personnel Costs .....\$ 6,000  
Consultant Costs ..... 3,000  
Equipment ..... 200  
Supplies .....  
Travel - Domestic .....  
- Foreign .....  
Patient Care - Inpatient .....  
- Outpatient .....  
Alterations and Renovations .....  
Consortium/Contractual Costs .....  
Trainee Stipends .....  
Trainee Tuition and Fees .....  
Trainee Travel .....

AWARD COMPUTATION  
DIRECT COSTS .....\$ 41,600  
INDIRECT COSTS .....\$ 8,000  
TOTAL .....\$ 49,600  
Less Unobligated Balance [Prior Period(s)] \$ 0  
AMOUNT OF THIS AWARD → \$ 49,600  
Base Dollars × Rate Percentage = Indirect Costs \$\*

TOTAL DIRECT COSTS → \$ 41,600

When PHS Prior Approval is required for rebudgeting, submit requests to Grants Management Official below.

SUPPORT RECOMMENDED FOR REMAINDER OF PROJECT PERIOD\*\*  
Budget Total Direct Costs Stipends  
Period (Includes Stipends)  
02 NONE

\*\*Subject to availability of funds and satisfactory progress.

REMARKS  
AMOUNT AWARDED IS THE MAXIMUM ALLOWABLE CEILING TO BE REIMBURSED UNDER THIS GRANT.

#GRANTS MANAGEMENT: MR BRUCE R. BUTRUM (301) 496-7467

SEE ATTACHED FOR TERMS OF ACCEPTANCE AND ANY ADDITIONAL TERMS AND CONDITIONS.

TERMS OF ACCEPTANCE: BY ACCEPTANCE OF THIS GRANT, THE GRANTEE AGREES TO COMPLY WITH THE TERMS AND CONDITIONS OF THE GRANT, INCLUDING THE FOLLOWING: (1) Special provisions noted above under remarks or attached to this notice (42 CFR Part 14.45 or 82, as applicable); (2) PHS Grants Administration Manual; (3) PHS Grants Policy Statement. The above order of precedence shall prevail.

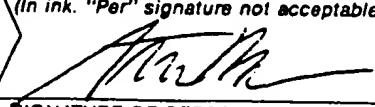
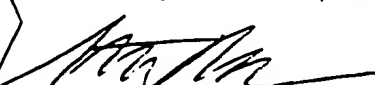
FY—Common Accounting Number 1-8425512	CRS/Entity Identification No. 1770207109A1	PHS List No./Object Class Code /41.4A	Document Number (08)R3DK44402A
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PROGRAM OFFICIAL

Charles A. Wells  
CHARLES A. WELLS, PH.D.  
DIRECTOR, DIABETES RES PROG.  
DIV OF DIABETES, ENDOCRINOLOGY  
AND METABOLIC DISEASES, NIDDK

PHS Grants Management Official  
Thomas G. Turley  
THOMAS G. TURLEY  
GRANTS MANAGEMENT OFFICER  
NAT INSTITUTE OF DIABETES AND  
DIGESTIVE AND KIDNEY DISEASES

EXPIRATION DATE 1/31/92

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE		LEAVE BLANK			
SMALL BUSINESS INNOVATION RESEARCH PROGRAM PHASE I GRANT APPLICATION		TYPE	ACTIVITY	NUMBER	
FOLLOW INSTRUCTIONS CAREFULLY		REVIEW GROUP		FORMERLY	
		COUNCIL/BOARD (Month/year)		DATE RECEIVED	
1. TITLE OF APPLICATION (Do not exceed 56 typewriter spaces) Microcomputer Attention Battery for School-age Children					
2. SBIR SOLICITATION NO <b>SBIR 91-2</b>					
3. PRINCIPAL INVESTIGATOR <input type="checkbox"/> New Investigator					
3a. NAME (Last, first, middle) Brown, Stephen James			3b. SOCIAL SECURITY NO. 539-66-5116		
3c. POSITION TITLE President, Raya Systems, Inc.			3d. MAILING ADDRESS (Street, city, state, zip code) 2570 West El Camino Real Suite 309 Mountain View, CA 94040		
3e. TELEPHONE (Area code, number and extension) (415) 949-3933					
4. HUMAN SUBJECTS <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES { <input checked="" type="checkbox"/> Exemption # 2, 3 OR <input type="checkbox"/> Form HHS 596 enclosed			5. VERTEBRATE ANIMALS <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES		
6. DATES OF PROJECT PERIOD From: 3/1/92 Through: 8/31/92			7. COSTS REQUESTED 7a. Direct Costs \$ 50,000 7b. Total Costs \$ 50,000		
8. PERFORMANCE SITES (Organizations and addresses) University of Nebraska-Lincoln Dept. of Educational Psychology 116 Bancroft Hall Lincoln, NE 68588  Raya Systems, Inc. 2570 West El Camino Real Suite 309 Mountain View, CA 94040			9. APPLICANT ORGANIZATION (Name, address, and congressional district) Raya Systems, Inc. 2570 West El Camino Real Suite 309 Mountain View, CA 94040 12th Congressional District		
			10. ENTITY IDENTIFICATION NUMBER 77-0207109		
			11. SMALL BUSINESS CERTIFICATION <input checked="" type="checkbox"/> Small business <input type="checkbox"/> Minority and disadvantaged <input type="checkbox"/> Woman-owned		
12. NOTICE OF PROPRIETARY INFORMATION The information identified by asterisks (*) on pages _____ of this application constitutes trade secrets or information that is commercial or financial and confidential or privileged. It is furnished to the Government in confidence with the understanding that such information shall be used or disclosed only for evaluation of this application; provided that, if a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information herein to the extent provided by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.					
13. DISCLOSURE PERMISSION STATEMENT If this application does not result in an award, is the Government permitted to disclose the title only of your proposed project, and the name, address and telephone number of the corporate official of your firm, to organizations that may be interested in contacting you for further information or possible investment? <input type="checkbox"/> YES <input type="checkbox"/> NO			14. CORPORATE OFFICIAL (Name, title, address and telephone number) Stephen James Brown, President Raya Systems, Inc. 2570 West El Camino Real, #309 Mountain View, CA 94040 (415) 949-3933		
15. PRINCIPAL INVESTIGATOR ASSURANCE: I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application. Willful provision of false information is a criminal offense (U.S. Code, Title 18, Section 1001).			SIGNATURE OF PERSON NAMED IN 3a (In ink. "Per" signature not acceptable) 		DATE 8/14/91
16. CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true and complete to the best of my knowledge, and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as the result of this application. A willfully false certification is a criminal offense (U.S. Code, Title 18, Section 1001).			SIGNATURE OF PERSON NAMED IN 14. (In ink. "Per" signature not acceptable) 		DATE 8/14/91

**ABSTRACT OF RESEARCH PLAN**

NAME, ADDRESS AND TELEPHONE NUMBER OF APPLICANT ORGANIZATION

Raya Systems, Inc.  
2570 West El Camino Real, #309  
Mountain View, CA 94040  
(415) 949-3933

EXHIBIT C  
PAGE 9 OF 11

YEAR FIRM FOUNDED

1988

NO. OF EMPLOYEES (include all affiliates)

8 (eight)

TITLE OF APPLICATION

**Microcomputer Attention Battery for School-age Children**

KEY PROFESSIONAL PERSONNEL ENGAGED ON PROJECT

NAME	POSITION TITLE	ORGANIZATION
Stephen Brown, PI	President	Raya Systems, Inc.
Todd Ramming	Project Manager	Raya Systems, Inc.
Gregg Wright, M.D., M.Ed.	Assoc. Prof. of Educ. Psych. & of Pediatrics	University of Nebraska- Lincoln and Omaha
Barbara Plake, Ph.D.	Director, Buros Inst. of Mental Measurements	University of Nebraska- Lincoln
Jerry Halpern, Ph.D.	Senior Research Associate	Stanford University Div. of Biostatistics

**ABSTRACT OF RESEARCH PLAN:** State the application's long-term objectives and specific aims, making reference to the health-relatedness of the project, describe concisely the methodology for achieving these goals, and discuss the potential of the research for technological innovation and commercial application. Avoid summaries of past accomplishments and the use of the first person.

The abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. Since abstracts of funded applications may be published by the Federal Government, do not include proprietary information. DO NOT EXCEED 200 WORDS.

It is widely accepted that children who fulfill the DSM-III-R criteria for Attention Deficit-Hyperactivity Disorder (ADHD) are a heterogeneous group, but reliable methods do not exist for defining identifiable homogenous subgroups. The proposed research will develop a microcomputer-based battery of tasks which will assess several aspects of auditory and visual attention in children between five and 14 years of age. As a primary objective, the battery should identify those ADHD children whose functioning of neuropsychologic mechanisms of attention is significantly impaired in comparison with a normal population. Secondly, it is aimed that of those children recognized as neuropsychologically deficient, nearly homogeneous subgroups may be identified in a way that is both statistically and clinically significant. These subgroupings will be indicators of which of the several neuropsychologic mechanisms participating in attention are to be suspected as primary deficits. Experts in educational psychology, psychological measurements and biostatistics will participate in the design and final critical assessment of the attention battery, and an informal trial will be carried out on about 20 children in Phase I to assess the feasibility of norming and validating the attention battery with controlled populations in Phase II.

Provide key words (8 maximum) to identify the research or technology.

"ADHD," "Attention Deficit," "Hyperactivity," "Computer," "Diagnostic Trial"

Provide a brief summary of the potential commercial applications of the research.

Evidence of the need for a diagnostic test beyond the subjective DSM-III-R criteria which is capable of identifying homogeneous subgroups of ADHD is manifested by the variability of diagnosis and treatment across physicians, teachers, parents and regions. The normed and validated diagnostic test to result from the proposed research would be of evident commercial application, both in pediatric use or in the screening clinic/school setting.

PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR: **Stephen Ja...**

BUDGET FOR PHASE I DIRECT COSTS ONLY					FROM 3/1/92	THROUGH 8/31/92	
PERSONNEL (Applicant organization only)		1 TYPE EMPL.	2 % OF EMPL.	3 EFFORT ON PROJ.	DOLLAR AMOUNT REQUESTED (Omit cents)		
NAME	ROLE IN PROJECT				SALARY	FRINGE BENEFITS	TOTALS
Stephen Brown	Principal Investigator	1.0	25%	0.25	42,000		\$10,500
Todd Ramming	programmer	1.0	40%	0.4	42,000		\$16,800
Jim Wehner	writer/artist	1.0	25%	0.25	30,000		\$7,500
SUBTOTALS							
CONSULTANT COSTS							
Gregg Wright, M.D., M.Ed., Univ. of Nebraska (50h @ \$100/h)							\$5,000
Barbara Plake, Ph.D., Univ. of Nebraska (10h @ \$100/h)							\$1,000
Jerry Halpern, Ph.D., Stanford University (10h @ \$100/h)							\$1,000
EQUIPMENT (Itemize)							
2 X IBM PC-compatible 386SX computer with SVGA graphics and monitor							\$5,500
2 X beyerdynamic audiometric calibrated headphones (DT 48-A)							\$500
Valentino royalty-free sampled sounds library							\$200
Sony 8-times oversampling CD-player with digital output							\$400
2 X SoundBlaster Pro Stereo Card (PC)							\$500
SoundBlaster development kit (software)							\$100
SUPPLIES (Itemize by category)							
miscellaneous computer supplies							\$500
TRAVEL							
DOMESTIC							
FOREIGN							
PATIENT CARE COSTS							
INPATIENT							
OUTPATIENT							
CONTRACTUAL COSTS							
OTHER EXPENSES (Itemize by category)							
freight (shipping of assembled attention battery unit to Nebraska performance site; routine close correspondence between sites in California and Nebraska via Federal Express)							\$500
TOTAL DIRECT COSTS (Also enter on page 1, item 7a)							\$
▶ This figure, when added to the indirect costs, may not exceed \$50,000.							\$50,000

OTHER GRANT AND  
CONTRACT SUPPORT  
(see instructions)

NO



YES

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE <b>NOTICE OF GRANT AWARD</b>	DATE ISSUED: <b>MAR 10 1992</b> GRANT NUMBER: HUD-1 (AHR-E 1 R43 HD29325-01 HLI TOTAL PROJECT PERIOD: From 03/10/92 Through 09/09/92
--	--

TYPE OF AWARD: SMALL BUSINESS INNOVATION RESEARCH PROG  
 AUTHORIZED BY: 42 USC 241 42 CFR PART 52 15 USC 638

AWARDED BY: NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Title of Project or Area of Training  
 MICROCOMPUTER ATTENTION BATTERY FOR SCHOOL AGE CHILDREN

Grantee Organization RAYA SYSTEMS INCORPORATED 2570 WEST EL CAMINO REAL SUITE 309 MOUNTAIN VIEW, CA 94040	Principal Investigator/Program Director/Awardee BROWN, STEPHEN J BS RAYA SYSTEMS INCORPORATED 2570 WEST EL CAMINO REAL SUITE 309 MOUNTAIN VIEW, CA 94040 12
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<b>APPROVED BUDGET</b> FOR BUDGET PERIOD 03/10/92 Through 09/09/92 Salaries and Wages .....\$ 34,800 Fringe Benefits ..... Total Personnel Costs .....\$ 34,800 Consultant Costs ..... 7,000 Equipment ..... 7,200 Supplies ..... 500 Travel - Domestic ..... - Foreign ..... Patient Care - Inpatient ..... - Outpatient ..... Alterations and Renovations ..... Consortium/Contractual Costs ..... Other ..... 500 Trainee Stipends ..... Trainee Tuition and Fees ..... Trainee Travel .....  TOTAL DIRECT COSTS → \$ 50,000	<b>AWARD COMPUTATION</b> DIRECT COSTS .....\$ 50,000 INDIRECT COSTS .....\$* 0 TOTAL .....\$ 50,000 Less Unobligated Balance [Prior Period(s)] \$ 0  <b>AMOUNT OF THIS AWARD</b> → \$ 50,000 Base Dollars × Rate Percentage = Indirect Costs \$*  <b>SUPPORT RECOMMENDED FOR REMAINDER OF PROJECT PERIOD**</b> <table style="width:100%;"> <tr> <td>Budget Period</td> <td>Total Direct Costs</td> <td>Stipends</td> </tr> <tr> <td>02</td> <td>(Includes Stipends)</td> <td>NONE</td> </tr> </table>	Budget Period	Total Direct Costs	Stipends	02	(Includes Stipends)	NONE
Budget Period	Total Direct Costs	Stipends					
02	(Includes Stipends)	NONE					

When PHS Prior Approval is required for rebudgeting, submit requests to Grants Management Official below.

\*\*Subject to availability of funds and satisfactory progress.

REMARKS

AMOUNT AWARDED IS THE MAXIMUM ALLOWABLE CEILING TO BE REIMBURSED UNDER THIS GRANT.

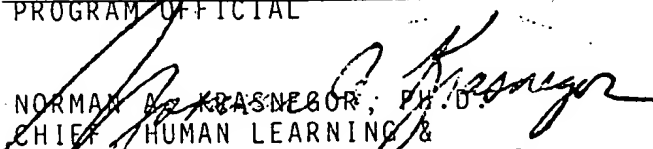
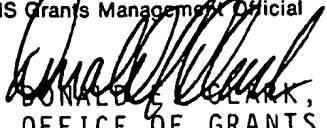
GRANTS MGMT CONTACT: CHARLETTE JEFFERSON (301)496-1303; FAX NO. (301)402-0915

PROGRAM CONTACT: REID LYON, PHD (301) 496-6591; FAX NO (301) 402-2085

SEE ATTACHED FOR TERMS OF ACCEPTANCE AND ANY ADDITIONAL TERMS AND CONDITIONS.

TERMS OF ACCEPTANCE: By acceptance of funds awarded under this grant, the grantee acknowledges that it will comply with the terms and conditions in the following: (1) Federal Acquisition Regulations cited above; (2) Special provisions noted above under remarks or attached to this notice; (3) 42 CFR Part 71 or 82, as applicable; (4) PHS Grants Administration Manual; (5) PHS Grants Policy Statement; (6) The Federal Acquisition Regulation; and (7) any other applicable regulations.

FY—Common Accounting Number 2-8421318	CRS/Entity Identification No. 1770207109A1	PHS List No./Object Class Code /41.4A	Document Number (08)R3HD29325A
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PROGRAM OFFICIAL  NORMAN A. BASNER, PH.D. CHIEF, HUMAN LEARNING & BEHAVIOR BR., CTR. FOR RES. FOR MOTHERS & CHILDREN, NICHD	PHS Grants Management Official  DONALD E. CLARK, CHIEF OFFICE OF GRANTS AND CONTRACTS NATIONAL INSTITUTE OF CHILD HLTH AND HUMAN DEVELOPMENT
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Project Plan

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# KinderCamit

*prepared by:*  
Steve Brown  
Jim Wehner

CONFIDENTIAL

© Copyright 1992

Raya Systems, Inc  
2570 West El Camino Real  
Suite 309  
Mountain View, CA 94040

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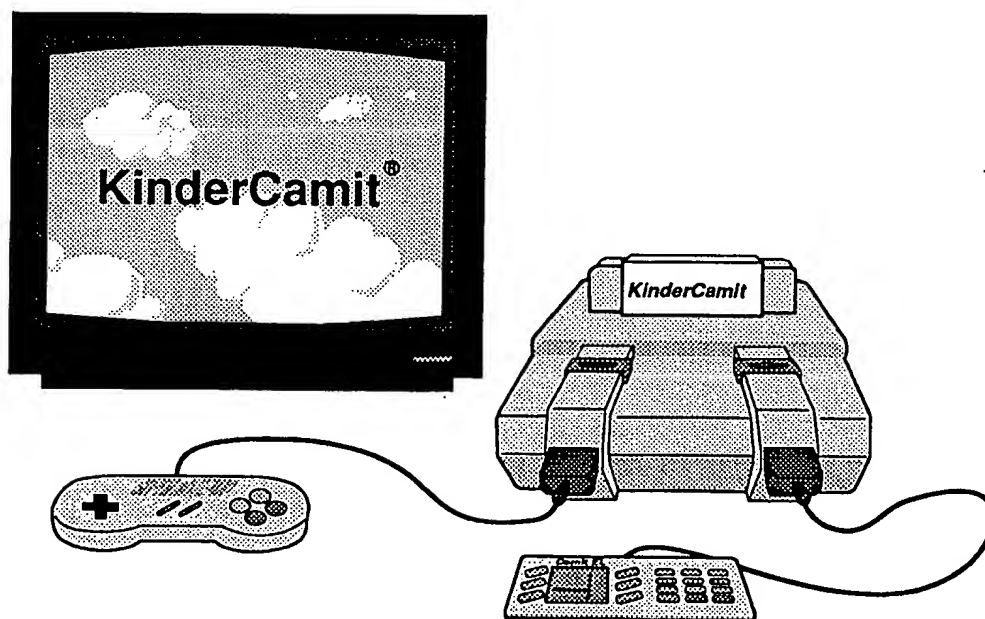
## **KinderCamit Preliminary Design Document**

### **Overview**

For the person with diabetes, the ability to receive feedback from efforts to maintain blood glucose levels within target ranges is an invaluable aid. Patients today use both paper and electronic logbooks for this purpose. There is much that the combination of an electronic logbook and a computer has to offer, making this feedback easy and up to the minute. However, many potential users are put off by the complexity and cost of a computer and software.

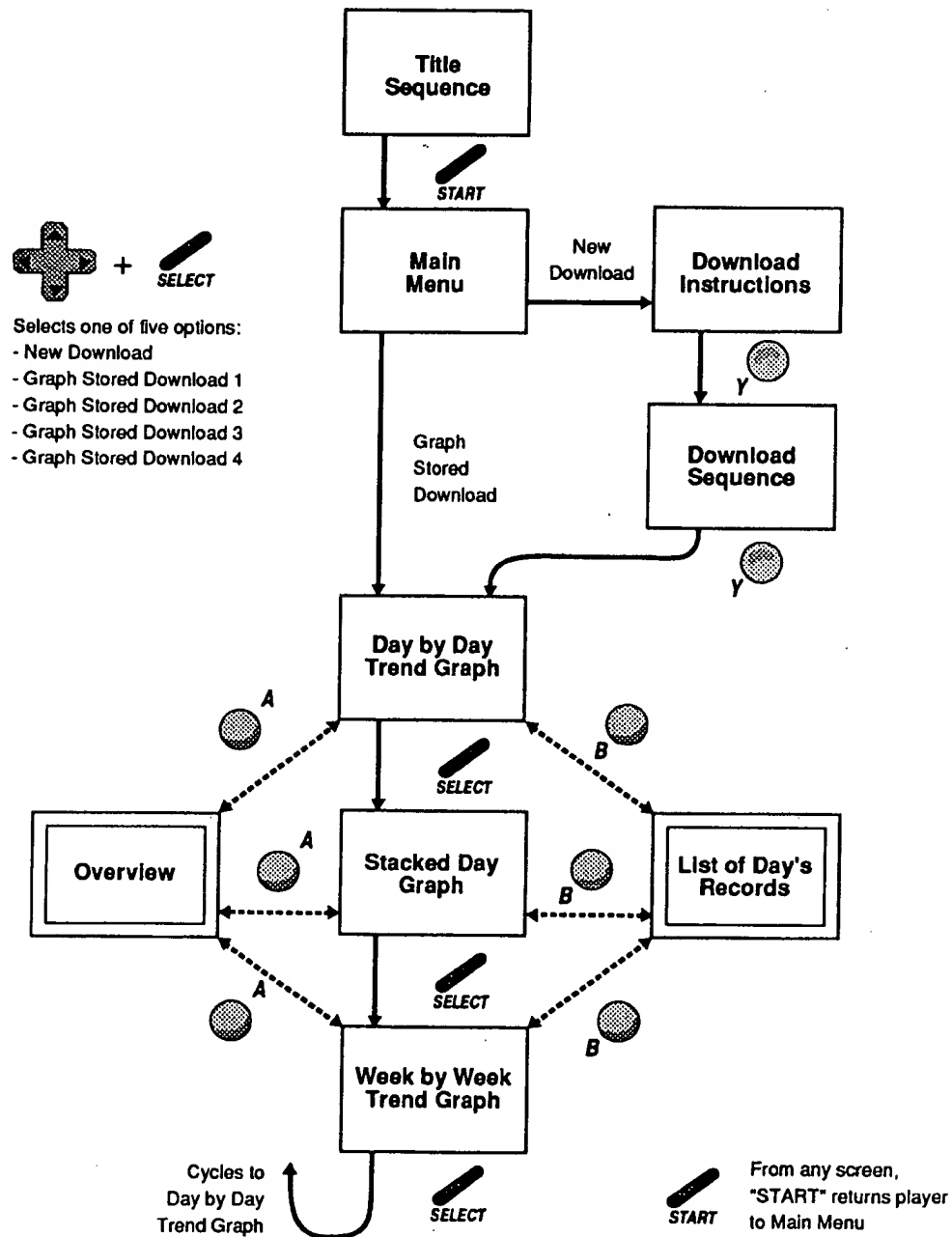
Using the Super Nintendo Entertainment System as a base, KinderCamit can provide such up-to-the minute, computer enhanced feedback without the cost or complexity associated with computers. KinderCamit takes information from the Camit EL electronic logbook, stores it, and displays this information in colorful and fun graphs and charts. All of this is done easily, quickly, and inexpensively.

KinderCamit is designed with children in mind, although it would be a useful tool for an adult or even for a physician explaining a treatment plan to a patient.



The system consists of the KinderCamit Super Nintendo Game Pak, A Super Nintendo Entertainment System, and a custom cable for attaching the Camit EL to the Super NES.

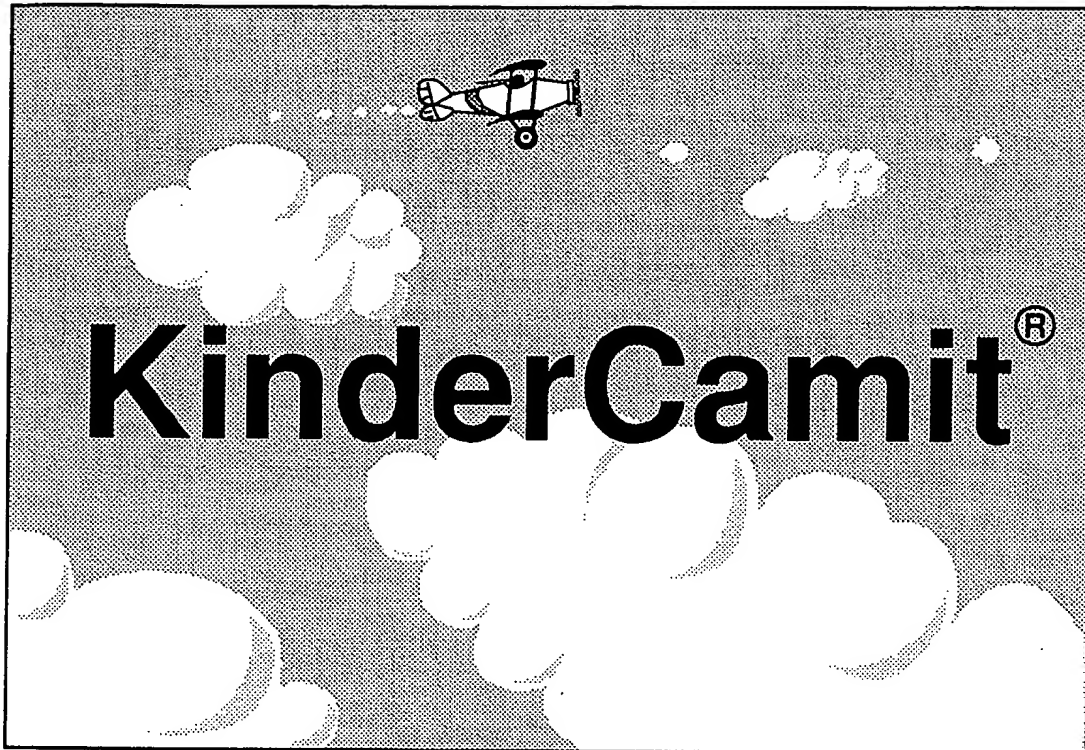
## KinderCamit -overview of screens



The screens in this diagram are explained in detail in the following sections.



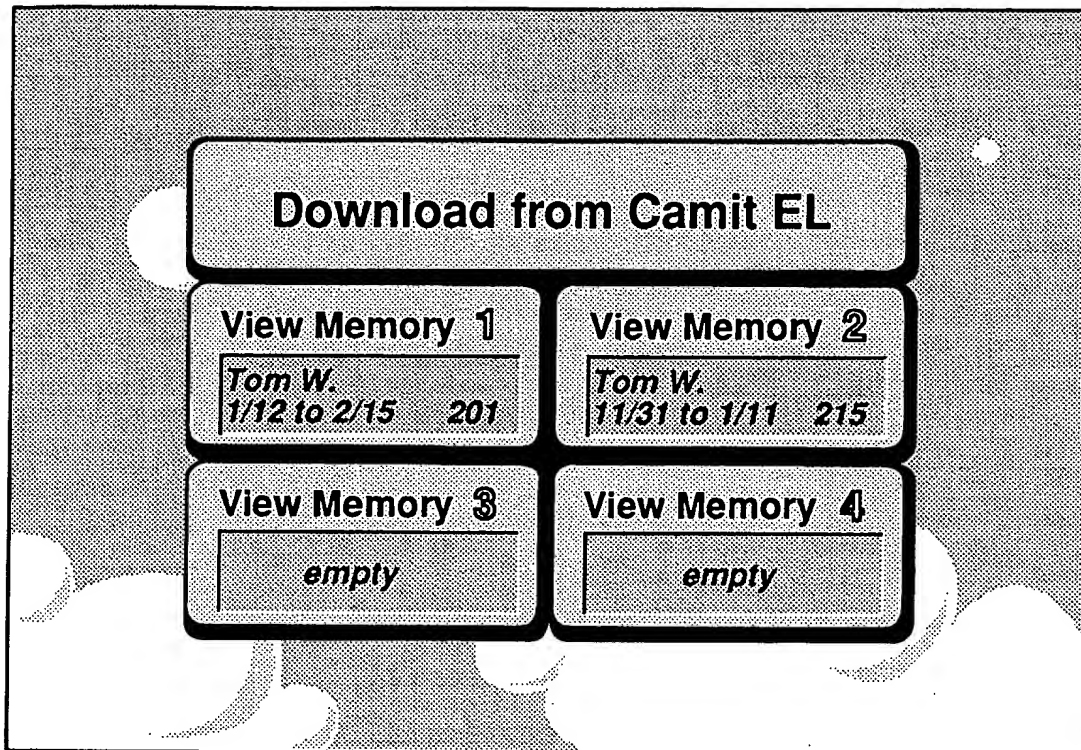
**Title Screen**



This screen will appear at power on. The jet fighter, biplane, and balloon from the three graphs periodically buzz through the picture. A corporate logo may be included easily.

Options: "start" -> main menu

## Main Menu

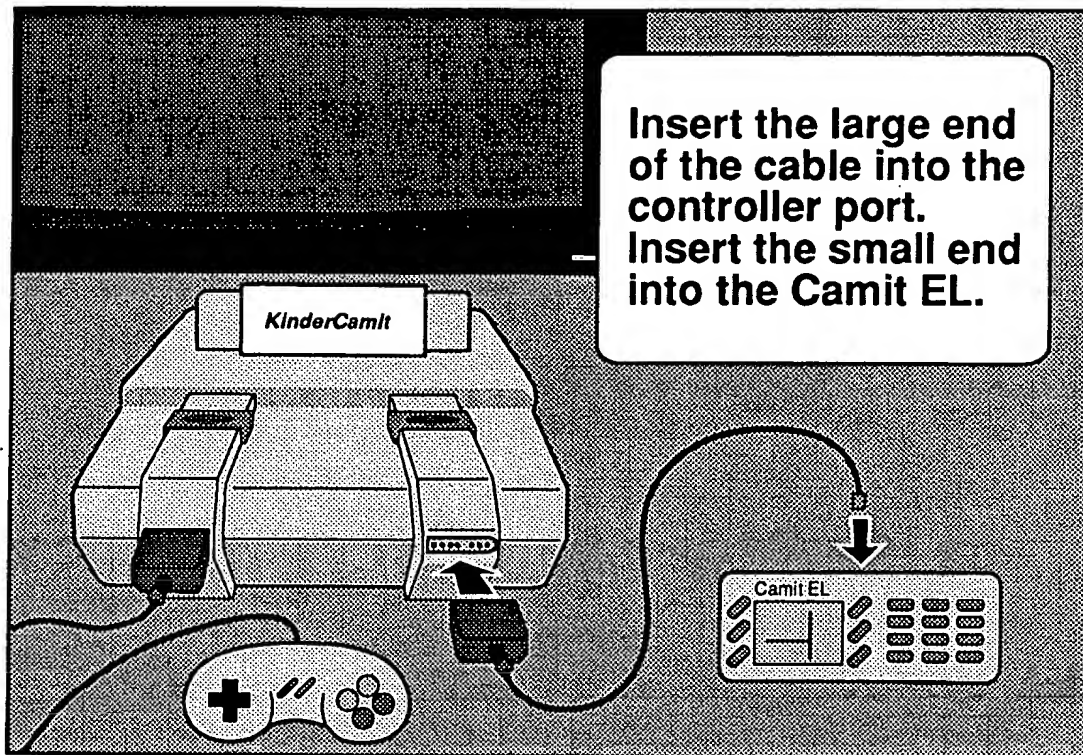


The main menu gives the player access to all the main functions of KinderCamit. A new download is initiated by highlighting the download button. Alternatively, any download in one of the four "memory slots" can be graphed. The player highlights the desired button with the directional controller and presses "select".

This main menu can be reached at any time by pressing the "select" button.

Options: directional controller & "select" to choose

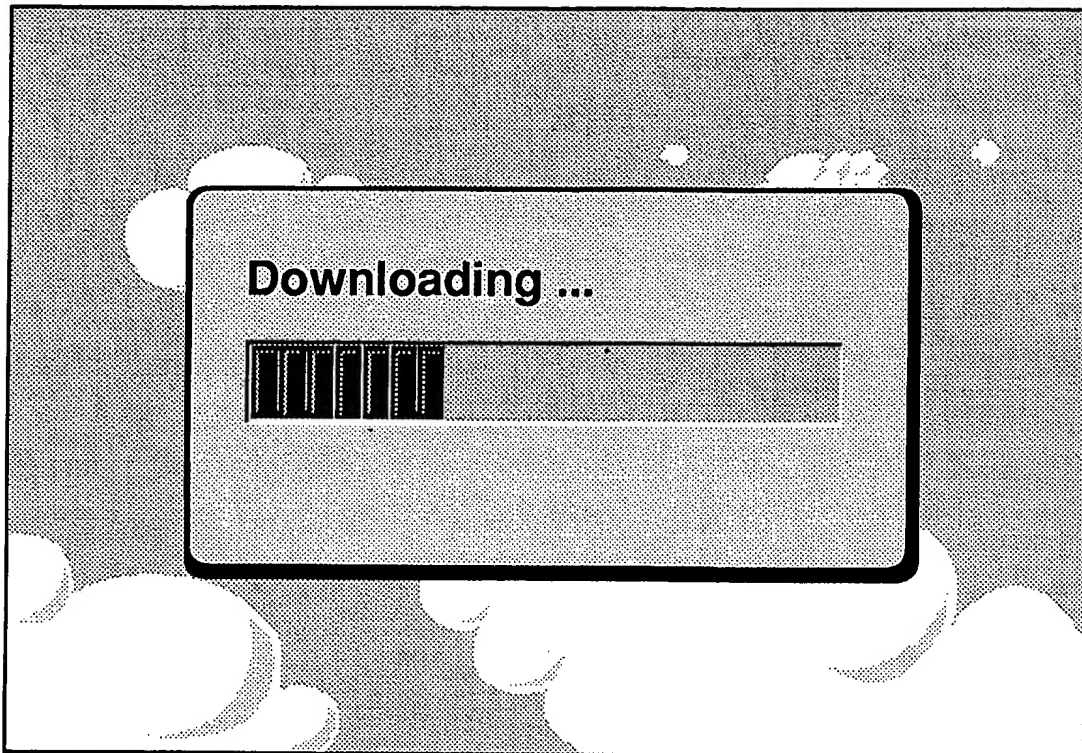
## Download Instructions



For ease of use, the simple task of attaching the Camit EL to the Super NES unit is graphically explained with this screen.

Options: "Y" -> download sequence

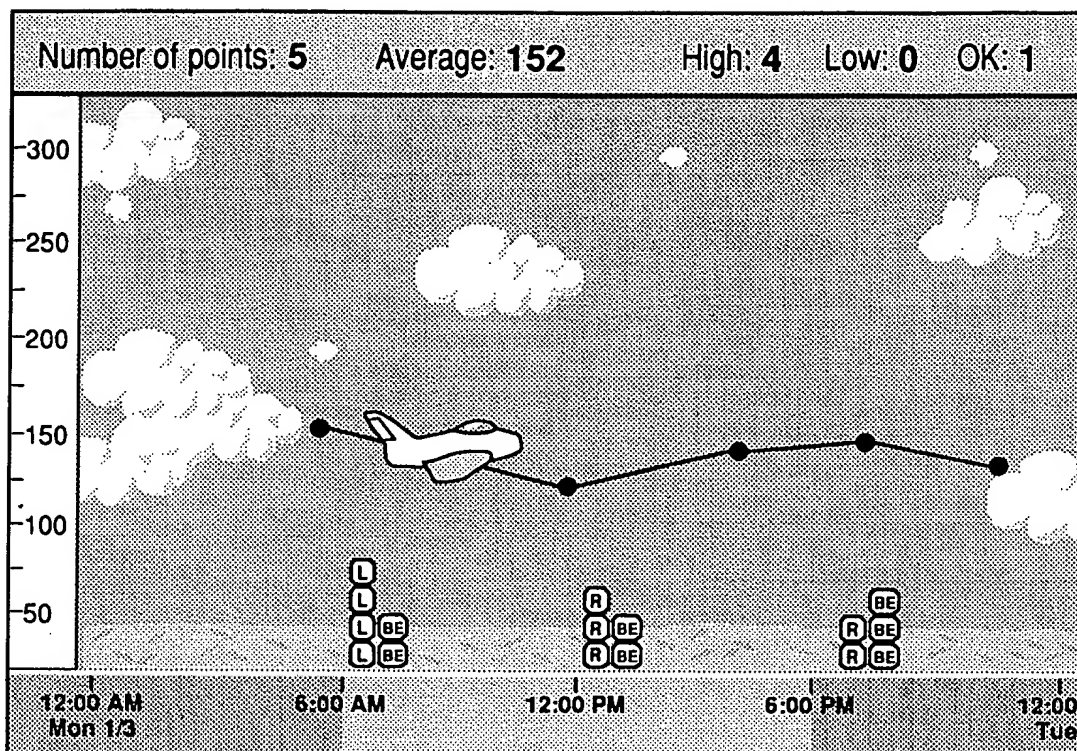
### Download Sequence



The progress of the download is displayed with this screen. When the download is complete, the total number of records download is displayed under the status bar.

Options: "Y" -> download sequence

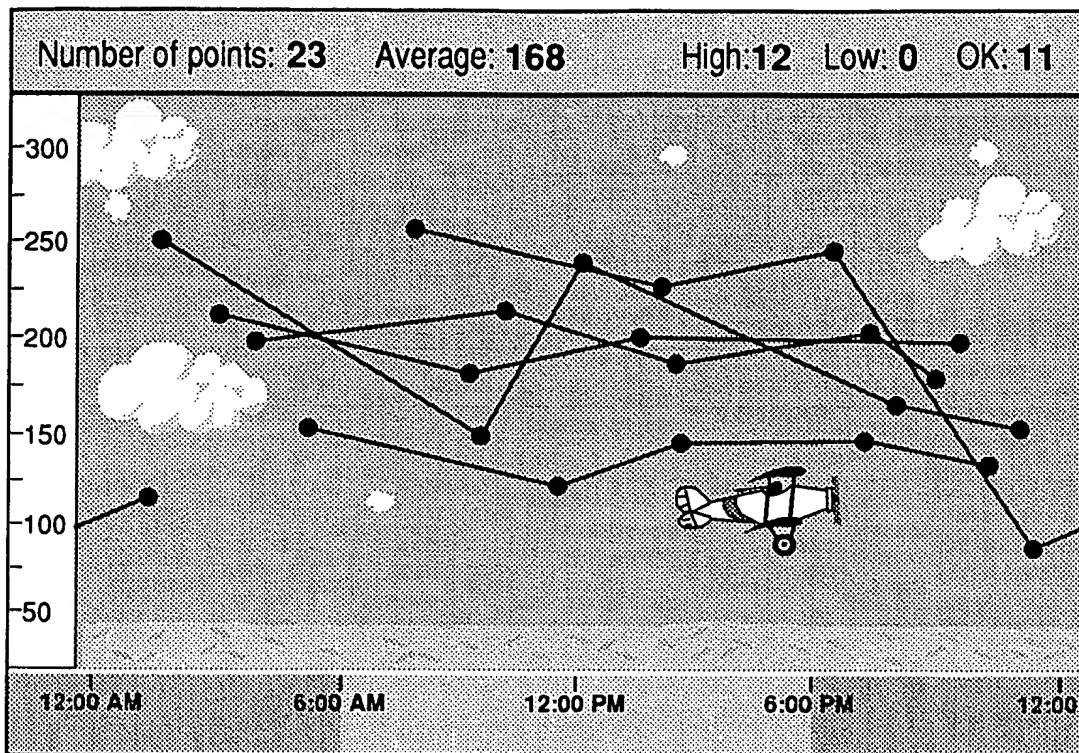
# **Day by Day Trend Graph**



The Day by Day graph presents the records from a download or memory slot in chronological order, one day at a time. The player can move the jet forward and backward along the graph. At hypoglycemic incidents, the plane bumps along the ground; hyperglycemic incidents cause the plane to spin out of control. Food and two types of insulin are marked with incremental histograms. Between-record intervals separated by enough time that a connecting line is not appropriate are obscured by clouds. The plane flies behind these clouds.

Options: "A" -> Overview Screen  
 "B" -> List of Day's Records  
 "select" -> Stacked Day Graph.

### Stacked Day Graph

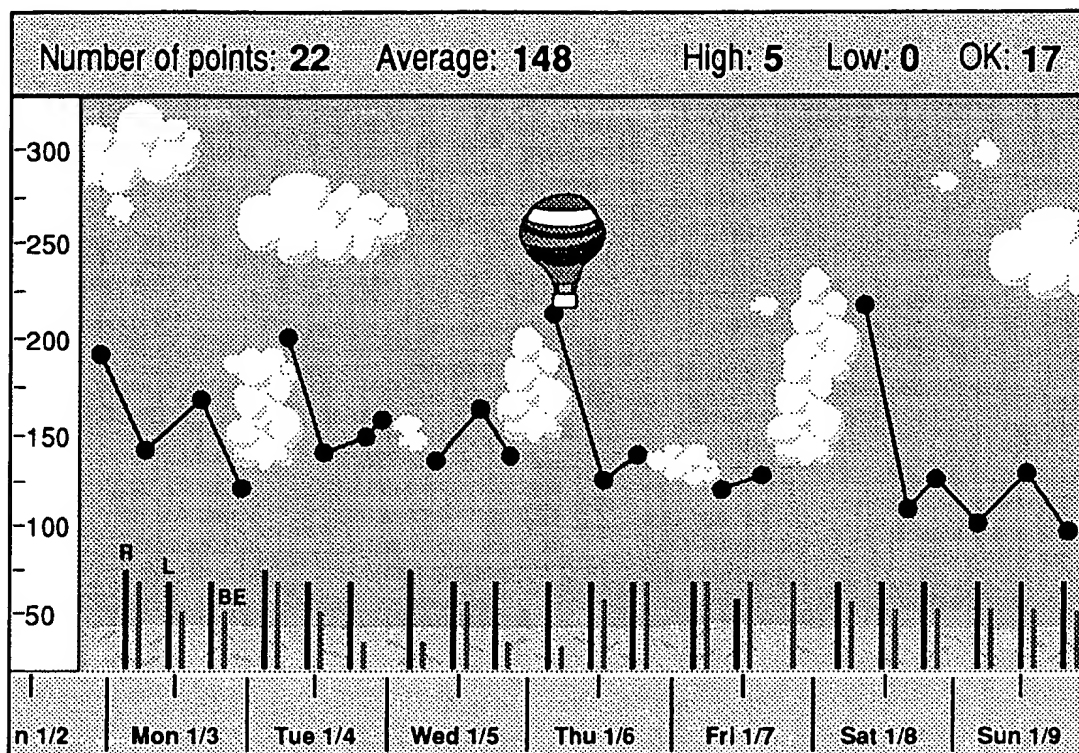


The Stacked Day graph presents each day's records from a download or memory slot overlayed on the same day's graph. The player can move the biplane up, down, forward and backward along the graph and the average for that time of day is displayed on the top line. The plane flies behind the clouds.

Options: "A" -> Overview Screen  
"B" -> List of Day's Records  
"select" -> Week by Week Graph.



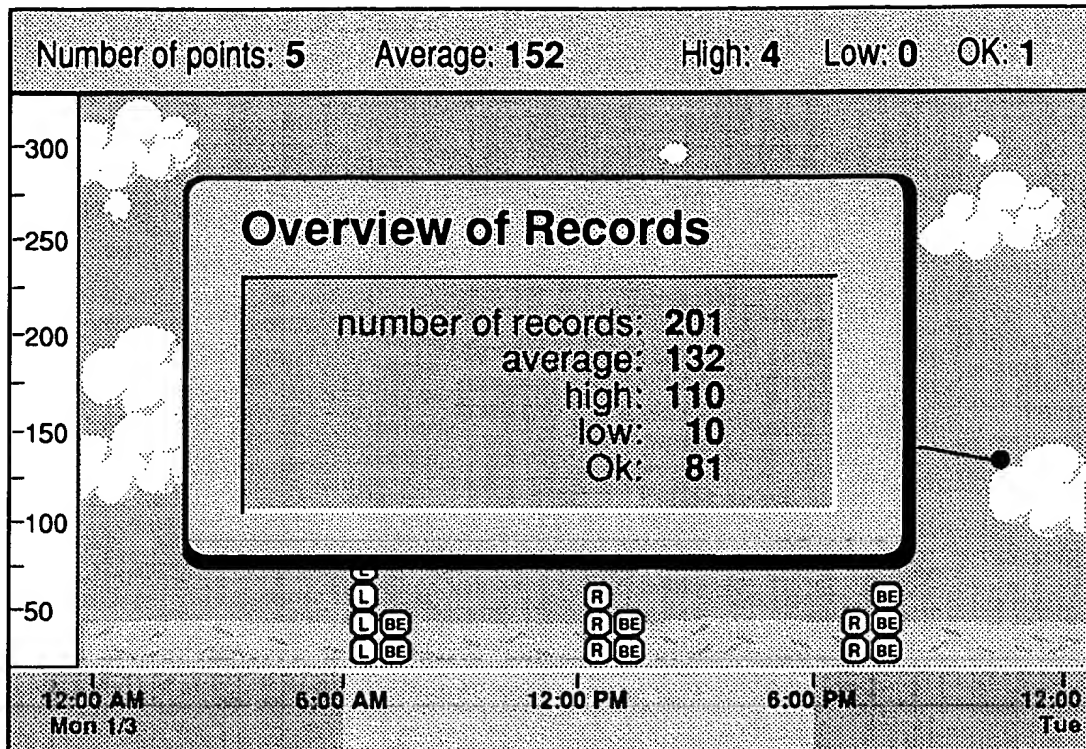
## Week by Week Graph



The Week by Week graph presents the records from a download or memory slot in chronological order, one week at a time. The player can move the balloon forward and backward along the graph. At hypoglycemic incidents, the balloon bumps along the ground; hyperglycemic incidents cause the balloon to spin out of control. Food and two types of insulin are marked with colored-line histograms. Between-record intervals separated by enough time that a connecting line is not appropriate are obscured by clouds. The balloon flies behind these clouds.

Options: "A" -> Overview Screen  
 "B" -> List of Day's Records  
 "select" -> Day by Day Graph.

### Overview Pop-up Box

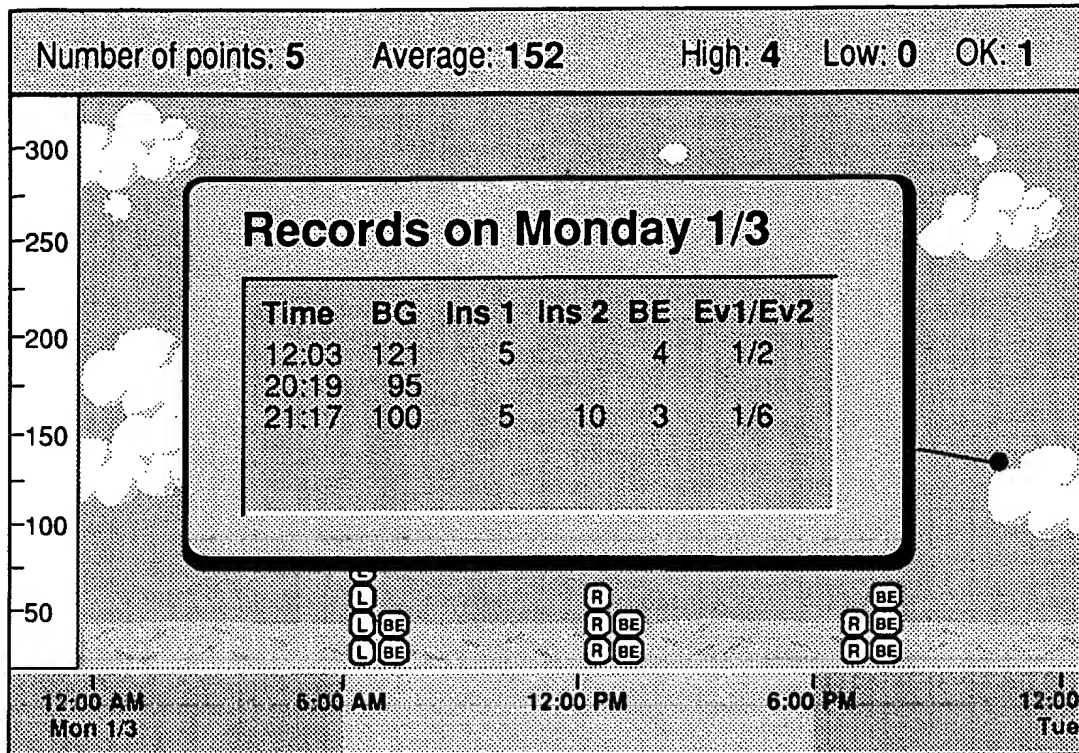


This box can be called up from any graph and displays statistics about all the records from the download or memory slot.

**Options:** "A" -> removes box



# List of Day's Records



This box can be called up from any graph and displays the records in text form from the day currently active (determined by the position of the plane or balloon).

Options: "A" -> removes box  
directional control -> scrolls list, if appropriate

03/25/92 12:31 FAX 206 682 6234

OLES MORRISON

**OLES, MORRISON & RINKER**

LAWYERS  
3500 Columbia Center  
701 Fifth Avenue  
Seattle, Washington 98104-7007  
(206) 623-3427

**FACSIMILE COVER SHEET**

Telecopier: (206) 682-6234

TO: Steve Brown

FAX: [REDACTED]

PHONE: [REDACTED]

CITY: Mountain View, CA

TO: \_\_\_\_\_

FAX: \_\_\_\_\_

PHONE: \_\_\_\_\_

CITY: \_\_\_\_\_

TO: \_\_\_\_\_

FAX: \_\_\_\_\_

PHONE: \_\_\_\_\_

CITY: \_\_\_\_\_

\*\*\*\*\*

FROM: Rich Black

CLIENT/MATTER: 6229 - 001

Page 1 of 4

DATE: 3/25/92

TIME: 12:30

TO REPORT ANY PROBLEMS WITH TRANSMISSION PLEASE CALL (206) 623-3427 - EXT. 639

DOCUMENT(S) TRANSMITTED: Draft letter.

MESSAGE: Steve I have not proofed or spell-checked this, but I think it addresses W's concerns. Call me before you send it to them.  
-Rich

Dear \_\_\_\_\_:

It was a pleasure meeting with you last Monday and enthusiasm and I am confident that work will be a success for Raya and an attractive new market.

tel

Fax

(425)

\_\_\_\_\_ appreciate your support  
\_\_\_\_\_ these projects a

As we discussed at our meeting, one primary area of concern about the game and my prospective investors is some assurance that Raya System's ideas are not swept up by another Nintendo licensee before we have a chance to convert those ideas into successful products. On the other hand, I appreciate your concern that you don't really know what your various licensees are working on until they present you with a nearly finished game, so you cannot really control what kind of games they may attempt to produce. I have some proposals that I think would adequately meet both of our concerns. First I will explain in more detail why Raya needs the proposal, then I will explain the proposal itself.

Why Raya & its investors need the assurance provided by my proposal.

You indicated that you don't think it is likely that any other licensee will attempt a health/education-related game that is of a quality that Nintendo would approve, basically because Nintendo has rejected most such attempts so far because of their overt commercialism and/or poor quality. However, if our games are successful, all other licensees would then be more interested, and by imitating the financing and production techniques Raya has conceived and developed, may be able to secure Nintendo's interest as well. This puts Raya and its investors in a very precarious position for several reasons.

1) The production of high quality and medically accurate health-related education games requires a great deal of research and testing prior to production. This research and testing inevitably involves a significant amount of public disclosure. For example, it is impossible to test the game on a statistically significant number of children and expect them to keep it a secret. Over the several weeks or months of research, we are confident that the information about our proposed game would leak to a competitor. Equipped with our idea, the competitor could then quickly produce a competing game without investing the time or money on the medical and educational research because it could free-ride on the research that Raya had done. The competitor could then come to you with a proposal for a less expensive game of comparable quality, and Raya would have a difficult time surviving the competition. In short, Raya needs to be assured that it can conduct all the research necessary for a medically and educationally accurate game without the fear of any competitors free-riding on the idea or the research.

2) In addition to the risk of free-riding on particular games or specific health-education issues, I am also concerned about the general concept that Raya is built on: health-education games financed by a corporate sponsor. Now that I have explained it and put all the pieces of the puzzle together, the concept seems simple. So simple in fact, that I am sure other competitors will attempt to imitate it before I have a chance to stabilize my position in the market. Others have come to you with games that were unacceptably commercialized or otherwise flops. But to my knowledge I am the first one to present you with a workable plan for securing a position for Nintendo in the health-education area. Before I go public with that plan, my investors and I need some assurance that none of our competitors will be able to free-ride on my idea and drive me out of the market before I have a chance to recover our initial investment.

3) Raya's investors (primarily the corporate sponsor's such as Novo Nordisk), are considering investing hundreds of thousands of dollars to place a Super Nintendo unit in every pediatrician office in the country. They are willing to do this because they hope to secure a return in public relations because of the target market becoming familiar with its name and associating that name positively with education. However, if, after spending all that money, one of their competitors produces a game to be played on the same Super Nintendo sets, that competitor would be able to free-ride on the first sponsor's investment. This would be unfair and the risk of that happening may discourage Raya's investor's (such as sponsors) from making the initial investment. In short, the investors need some assurance that they can earn an adequate return on this initial capital investment.<sup>1</sup>

4) The health-education related game market is very promising, but relative to the game market in general, is quite narrow. Most Nintendo licensees can survive severe competition in the general game market because there are some \_\_\_\_\_ million kids that will play any type of game. Raya's proposed games however, are intended to serve a much more specialized market. The asthma game, for example, even assuming an optimistic market penetration of \_\_\_\_\_ %, would only sell \_\_\_\_\_ copies. This number is so small that I am quite concerned that it would not support more than one producer. This is even more true with respect to the Diabetes game. At least for the foreseeable future, I plan to focus on health-education related games, and am making a conscious decision to restrict my production to this narrow market. In return, my investors and I need some assurance that my fledgling firm can afford to invest in this specialized market without competition from bigger and more established licensees that can afford to risk a loss in this narrow market because they can offset the loss with gains in the general game market.

A proposal providing Raya and its investors the assurance they need to go forward with the games

1) My basic proposal is to have Nintendo grant me a conditional exclusive license to produce games in the health-education area for 2 years. The conditions would be these:

a) That it can be made non-exclusive if Raya ever fails to produce games of the quality and in the quantity that Nintendo requires. This protects you from two risks: 1) my products become inferior and you would want the opportunity to have a different licensee produce health-education games. I certainly don't expect this to happen, but you are entitled to protect yourself from that risk. 2) Raya cannot produce sufficient quantity to meet the demand. This protects you from the possibility that a truly successful product is not optimally marketed because of Raya's size, and would give you the option of allowing a different licensee to fill the gap with a competing product.

b) That it be subject to all the conditions of my current license agreement. For example, it would be restricted to North America.

<sup>1</sup> One possible way of addressing this would be for the investors to demand a promise from the pediatricians that they only play the investors' games on their units, and not play any games of competitors. This is inferior to my proposal because 1) it would be very difficult to monitor and police, 2) it would be very difficult to get the pediatricians to make such a promise, 3) it would be a wasteful duplication of resources to create incentives to have a different Super Nintendo set for each different game in each pediatrician's office; it makes much more sense to have one or a few units which can be used to play any health-related educational game in the office.

c) That it would become non-exclusive after 2 years. I and my investors would actually prefer 3 years but we may be able to establish a solid market position within 2 years, and I may be able to persuade my investors to accept only 2 years.

d) That it would only be for the health-education related field. Even broadly-defined (we could work out the wording together), this field is very narrow relative to the entire market available to other Nintendo licensees, so it would work little, if any, hardship on them.

e) That every other Nintendo licensee be notified of Raya's exclusive conditional license as soon as it is granted. This will prevent them from investing time or money in games in the health-education related field only to find out later that it was restricted and that you would not permit it because of your license agreement with me. This not only saves them money, but is fair. It also will remove the temptation for the licensees to try to persuade you to dishonor your agreement with me. I don't expect that you would do that, but I think it would be better if you were not even bothered by such solicitations. The notice could say something like:

"Dear Nintendo Licensee, please take notice that we will not be approving any games produced by you in the health-education field for the next 2 years by reason of an exclusive conditional license agreement we have entered into with another licensee. If you have any question about whether a contemplated game will be considered by us as falling within the health-education field, we recommend that you contact us at the earliest possible date so as to avoid wasted effort by you. If the exclusive conditional license agreement is broken or otherwise becomes non-exclusive, we will notify you immediately."

f) A final optional condition is that it could contain a first right of refusal for Raya. That is, instead of a blanket prohibition on any health-education related games, our license could grant us a first right of refusal to produce any games in the health-education field that are proposed to you. So the first two sentences of the notice would instead read something like this:

"Dear Nintendo Licensee, please take notice that ideas for any games to be produced by you in the health-education field for the next 2 years are subject to a first right of refusal by reason of an exclusive conditional license agreement we have entered into with another licensee. We will only approve games on topics in the health related field produced by you if our exclusive licensee refuses to agree within 60 days to produce a game on that topic. . .

### Summary

The proposal accommodates, I think, both our concerns. By virtue of all the conditions on the proposed exclusivity of the license, I also think it is quite reasonable. As I indicated both in this letter and when we met, this matter is of the utmost importance to me, and I hope you will find the proposal acceptable. Of course, if you have any modifications or alternate proposals that would address my (& my investors') needs, I would be happy to discuss them with you.

I look forward to hearing from you.

Sincerely,

\_\_\_\_\_  
Stephen Brown

OLES, MORRISON & RINKER  
LAWYERS  
ACCOUNTING DEPT. 3011  
P.O. BOX 34936  
SEATTLE, WASHINGTON 98124-1936  
(206) 623-3427

EXHIBIT F  
PAGE 2 OF 4

FEDERAL ID NO. 91-0574243

May 13, 1992

RAYA SYSTEMS

Invoice 58596 Page 2

04/08/92 Review Correspondence file & contracts.  
RB .40 hrs.

04/09/92 Review Correspondence file & old contracts; Legal  
Research regarding smoke; Call to client.  
RB 2.10 hrs.

04/10/92 Legal Research regarding T. Mark &  
Copyright; Telephone call to Louise regarding  
status.  
RB .80 hrs.

04/18/92 Legal Research regarding trademark, copyright &  
smoke.  
RB 1.50 hrs.

04/20/92 Legal Research regarding trademark, copyright &  
smoke; Status conference with Steve regarding  
research, etc.  
RB .50 hrs.

04/21/92 Telephone call from Steve; Memorandum to  
file; Review BM contract.  
RB 1.60 hrs.

04/22/92 Review BM contract; Telephone call to S. Brown  
regarding promo clauses.  
RB .70 hrs.

Fees for legal services.....\$ 1800.00

ADVANCED COSTS

04/07/92 Federal Express: Delivery to Mr. S.	\$	10.50
Brown, 3/26/92. RTB		
Postage/Telecopy	\$	12.61
Telephone Charges	\$	2.82
Photocopies	\$	6.40
Word Processing	\$	35.00

Total Costs.....\$ 67.33

Total fees and costs.....\$ 1867.33

LES, MORRISON & RINKER  
LAWYERS

ACCOUNTING DEPT. 3011  
P.O. BOX 34936  
SEATTLE, WASHINGTON 98124-1936  
(206) 623-3427

EXHIBIT F  
PAGE 3 OF 4

FEDERAL ID NO. 91-0574243

May 13, 1992

Invoice # 58596 Page 3

RAYA SYSTEMS

PLEASE REMIT TOTAL BALANCE DUE.....\$ 1867.33

This invoice may not include expense items for which we have not yet been billed.

OLES, MORRISON & RINKER  
LAWYERS  
ACCOUNTING DEPT. 3011  
P.O. BOX 34936  
SEATTLE, WASHINGTON 98124-1936  
(206) 623-3427

EXHIBIT F  
PAGE 1 OF 4

FEDERAL ID NO. 91-0574243

May 13, 1992  
Invoice 58596 Page 1

RAYA SYSTEMS  
2570 W EL CAMINO REAL  
SUITE 309  
MT VIEW CA 94040

Our File #C6228-001 For Services Through 04/22/92  
Miscellaneous

03/23/92	Review contracts & business strategy with S.Brown. DSO	1.60 hrs.
03/23/92	Office conference with S.Brown regarding contracts & business strategy. RB	1.80 hrs.
03/24/92	Telephone call to S.Brown regarding follow up of meeting;Preparation of Letter to Nintendo. RB	.60 hrs.
03/25/92	Draft Letter to Nintendo regarding excl. license;Revise CS Agreement. RB	4.00 hrs.
03/26/92	Review corporate sponsor contract & Revise. DSO	.30 hrs.
03/26/92	CS Agreement;Revise contracts. RB	1.40 hrs.
03/27/92	Schedule contract review. RB	.10 hrs.
03/30/92	Review billing Memorandum. RB	.20 hrs.
04/02/92	Office conference with KMM regarding general corporate paperwork. RB	.10 hrs.
04/07/92	Review file;Develop annual corp. legal administrative plan. RB	.40 hrs.

#2215



RAYA SYSTEMS, INC.  
2570 W. EL CAMINO REAL #309  
MOUNTAIN VIEW, CA 94040

BANK OF AMERICA NT & SA  
SAN ANTONIO BRANCH 0448  
P.O. BOX 340  
MOUNTAIN VIEW, CA 94042  
11-35/1210

2219

2 Jun 92

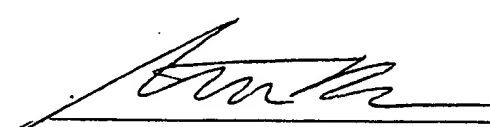
Pay to the  
Order of Oles, Morrison & Rinker

\*\*\*1,867.33

thousand Eight Hundred Sixty-Seven and 33/100\*\*\*\*\*

Dollars

Oles, Morrison & Rinker  
Lawyers  
Accounting Dept. 3011  
P.O. Box 34936  
Seattle, Washington 98124-1936



⑈002219⑈ ⑆121000358⑆ 04482⑈15097⑈

⑈0000186733⑈

FAX 05/11/92

to: Hartmut Kassulke  
Boehringer Mannheim GmbH  
phone: (621) 759-3997  
fax : (621) 759-4179

pages: 2 (including this one)

from: Todd Ramming  
Raya Systems, Inc.  
phone: (415) 949-3933  
fax : (415) 949-3935

re: Camit S 2.5

Dear Hartmut,

Thank you for your fax today, and I enjoyed speaking with you. Below I present specifics on our timetable for development of Camit S 2.5.

	B	C	D	E
#1 May 11-15	technical upgrades			
#2 May 18-22	database/conversion <sup>a</sup>			
#3 May 25-29	""			
#4 Jun 1-5	downloading			
#5 Jun 8-12	import			
#6 Jun 15-19	interface/algorithms			
#7 Jun 22-26	""			
#8 Jun 29-3	""			
#9 Jul 6-10	"" <sup>b</sup>			
#10 Jul 20-24	multi-user	revised costs to BM <sup>1</sup>		
#11 Jul 27-31	debugging	acceptance by BM		
#12 Aug 3-7	multi-user	user guide		
#13 Aug 10-14	installation	""		formal testing <sup>b</sup>
#14 Aug 17-21	debugging <sup>c</sup>	"" <sup>d</sup>	revised costs to BM <sup>2</sup>	
#15 Aug 24-28		""	acceptance by BM	formal testing
#16 Aug 31-4		"" <sup>e</sup>	Netware lite app.	""
#17 Sep 7-11			""	""
#18 Sep 14-18			"" <sup>f</sup>	"" <sup>g</sup>

1 costs revised to provide a new integrated edition of the user guide with enhancements and changes highlighted

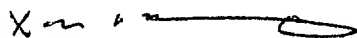
2 costs revised to provide discussion of use of Camit S in a networked environment with specific reference to NetWare lite

- a first application enhanced sent to BM
- b test plan sent to BM
- c second application enhanced sent to BM
- d draft user guide sent to BM
- e proof user guide sent to BM
- f proof NetWare lite example sent to BM
- g final report sent to BM, with final deliverables

Please let me know your comments. I will provide you, in addition to the indicated deliverables, bi-weekly status reports of our progress by fax, and look forward to speaking with you during the completion of this work.

Also, I have a question still remaining from our discussion by phone. In regard to the "marking" byte, is this not still where C (=changed) and M (=manual) are indicated -- information present in the EL as well ?

Best regards,



Todd Ramming

---

# Facsimile Cover Sheet

**To:** Amy Phillips  
**Company:** 52nd Annual Scientific Sessions -  
Manager  
**Phone:** 703-549-1500 #349  
**Fax:** 703-836-7439

**From:** Stephen J. Brown  
**Company:** Raya Systems, Inc.  
**Phone:** 415-949-3933  
**Fax:** 415-949-3935

**Date:** 05/12/92  
**Pages including this  
cover page:** 2

**Comments:**

*Executed 5/12 3:45 pm*



52ND ANNUAL SCIENTIFIC SESSIONS

SPEAKER RELEASE FORM

All symposia of the 52nd Annual Scientific Sessions will be audio-taped for the purpose of selling the audiotapes, contingent upon approval of the speakers.

Please complete and return this form to ADA to authorize audio-taping and sale of the tape of your presentation.

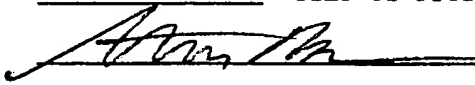
  X   Yes, you may audio-tape my presentation and sell the audiotape. I understand I will receive no royalties for this use.

       No, you may not audio-tape my presentation.

Presenter's Name (Print): Stephen J. Brown

Title of Presentation: New Technology for Diabetes Education:  
Home Video Games

Date of Presentation: June 22 '92 Time of Presentation: 1:45pm

Presenter's Signature: 

Please complete and return this form by May 15, 1992 to:

Amy Phillips  
52nd Annual Scientific Sessions Meeting Manager  
American Diabetes Association  
National Center  
1660 Duke Street  
Alexandria, VA 22314  
USA  
Telephone: 703/549-1500, ext. 349  
Fax: 703/836-7439  
Telex: 901132



National Center 1660 Duke Street Alexandria, Virginia 22314 (703) 549-1500 Telex: 901132 Fax: (703) 836-7439  
May 4, 1992

Steve Brown  
President  
Raya Systems  
688 Josina  
Palo Alto, CA 94306

Dear Mr. Brown:

We are very pleased that you have accepted the invitation to participate in the American Diabetes Association's 52nd Scientific Sessions to be held June 20-23, 1992 in San Antonio, Texas. Your symposium is scheduled to be held Monday, June 22 from 1:45 p.m. - 3:45 p.m. at the San Antonio Convention Center. An Advanced Program is enclosed for your information, and includes registration and housing forms.

As a speaker, your registration fee will be waived; however, you must register for the meeting by completing the enclosed form. ADA will not reimburse travel or expenses. In addition, ADA now requires all speakers to complete a disclosure statement that addresses your relationship(s) with other organizations/industries which you will find enclosed.

All sessions will be taped. Please complete the enclosed speaker release form and audio visual request form and return to the Meetings Department as soon as possible. Also note that sessions will be held in large halls in the San Antonio Convention Center. Please make every effort to ensure that your slides will be clearly visible to all attendees. A guide for making good quality slides is enclosed.

In order to include the correct information concerning your participation in the promotional materials for the '92 meeting, please complete the enclosed form and return it to me as soon as possible.

If you have any questions concerning the program or the meeting, please contact me at 703/549-1500, x281.

We look forward to your participation in the program.

Sincerely,

Linda Cann  
Manager, Professional Programs

Enclosures

---

**Officers**

Todd E. Leigh  
*Chairman of the Board*

Jay S. Skyler, M.D.  
*President*

Madelyn L. Wheeler, R.D., M.S., C.D.E.  
*Senior Vice President*

Ross V. Hickey, Jr.  
*Chairman of the Board-Elect*

F. Xavier Pi-Sunyer, M.D.  
*President-Elect*

Michael A. Greene  
*Vice Chairman of the Board*

James R. Gavin, III, M.D., Ph.D.  
*Vice President*

Patricia Stenger, R.N., C.D.E.  
*Vice President*

Marilyn Moore  
*Secretary*

Stephen J. Satalino  
*Treasurer*

**Office of the Executive**

John H. Graham, IV  
*Chief Executive Officer*

Richard Kahn, Ph.D.  
*Chief Scientific and Medical Officer*

Caroline Stevens  
*Chief Operating Officer*

OLES, MORRISON & RINKER  
LAWYERS  
ACCOUNTING DEPT. 3011  
P.O. BOX 34936  
SEATTLE, WASHINGTON 98124-1936  
(206) 623-3427

FEDERAL ID NO. 91-0574243

# 302  
EXHIBIT I  
PAGE 1 OF 4

June 10, 1992  
Invoice 58970 Page 1

RAYA SYSTEMS  
2570 W EL CAMINO REAL  
SUITE 309  
MT VIEW CA 94040

Our File #C6228-001  
Miscellaneous

For Services Through 05/22/92

04/23/92	Revise CS Agreement; Preparation of Memorandum to Steve regarding status of contracts & obligations thereunder	RB	2.40 hrs.
04/24/92	Review Letter to Steve regarding contracts; Review Steve's Letter re Todd's share; Drafting of reply.	RB	1.10 hrs.
04/30/92	Review billing memo.	RB	.20 hrs.
05/05/92	Telephone call from Steve regarding contracts, board of directors & general business matters.	RB	.40 hrs.
05/05/92	New contract with Sculptured; Review new publisher contract.	RB	.40 hrs.
05/06/92	Review new development contract; Telephone call from Steve regarding contracts.	RB	.70 hrs.
05/08/92	Review new developer contract.	RB	2.40 hrs.
05/11/92	Telephone call to Steve regarding comments regarding contract.	RB	.40 hrs.
05/12/92	Review new developer contract provisions.	DSO	.20 hrs.

OLSEN, MORRISON & RINKER  
LAWYERS  
ACCOUNTING DEPT. 3011  
P.O. BOX 34936  
SEATTLE, WASHINGTON 98124-1936  
(206) 623-3427

FEDERAL ID NO. 91-0574243

June 10, 1992  
Invoice 58970 Page 2

RAYA SYSTEMS

05/12/92	Further Review Letter to Steve regarding risks under New Sculptured contract; Review artist contract. RB	4.50 hrs.	
05/13/92	Letter to S.Brown regarding Sculptured contract; Telephone conf. with S.Brown regarding Letter. RB	1.50 hrs.	
05/14/92	Telephone call to Louise regarding contract. RB	.10 hrs.	
05/15/92	Review Correspondence with Structured in preparation for negotiations. DSO	.10 hrs.	
05/15/92	Telephone call to S.Brown regarding Letter to Sculptured. RB	2.10 hrs.	
05/18/92	Call to Raya regarding Receipt of fax. RB	.10 hrs.	
05/19/92	Review Corp. maint. documents & contracts; Office conference with DSO; Preparation of Letter to S.Brown. RB	2.90 hrs.	
05/20/92	Drafting of Letter to S.Brown; Notice of confid. empl. Agreement / employment Agreement. RB	3.90 hrs.	
05/20/92	Telephone call from S.Brown regarding Sculptured's response to objections; Telephone call to G.Metos. RB	3.00 hrs.	
05/21/92	Revise Sculptured's prop. contract; Drafting of Corp. maintenance Letter; Telephone call from Steve regarding contract. RB	4.50 hrs.	
Fees for legal services.....\$			2808.00
<u>ADVANCED COSTS</u>			
05/11/92	Federal Express: Delivery to S. Brown, \$	8.00	
4/23/92. RTB			



OLES, MORRISON & RINKER  
LAWYERS  
ACCOUNTING DEPT. 3011  
P.O. BOX 34936  
SEATTLE, WASHINGTON 98124-1936  
(206) 623-3427

FEDERAL ID NO. 91-0574243

RAYA SYSTEMS

June 10, 1992  
Invoice # 58970 Page 3

Postage/Telecopy	\$	67.23	
Telephone Charges	\$	45.95	
Photocopies	\$	9.20	
Word Processing	\$	233.00	
Total Costs.....	\$		363.38

Total fees and costs.....	\$	3171.38
PLEASE REMIT TOTAL BALANCE DUE.....	\$	3171.38

This invoice may not include expense items for which we have not yet been billed

RAYA SYSTEMS, INC.  
2570 W. EL CAMINO REAL #309  
MOUNTAIN VIEW, CA 94040

BANK OF AMERICA NT & SA  
SAN ANTONIO BRANCH 0448  
P.O. BOX 340  
MOUNTAIN VIEW, CA 94042  
11-35/1210

2297

30 Jun 92

Pay to the  
Order of

Oles, Morrison & Rinker

\$ \*\*\*\*\*3,171.38

Three Thousand One Hundred Seventy-One and 38/100\*\*\*\*\*

Dollars

Oles, Morrison & Rinker  
Lawyers

Accounting Dept. 3011

P.O. Box 34936

Seattle, Washington 98124-1936

Invoice #58970



⑈002297⑈ ⑆121000358⑆ 04482⑈15097⑈

⑈0000317138⑈

# Fax Transmission

Raya Systems, Inc.  
2570 West El Camino Real  
Suite 309  
Mountain View, California 94040

Telephone (415) 949-3933  
Fax (415) 949-3935

Sender Steve Brown  
Subject \_\_\_\_\_  
Date 5/31/92  
Pages 2

---

## Please deliver to

Name Hartmut Kaßulke  
Department SP-MP  
Company Boehringer Mannheim  
Fax number 011 49 621 759 4179

June 1, 1992

Hartmut Kassulke  
Boehringer Mannheim GmbH  
Abt. SP-MP  
Mannheim, Germany

Dear Hartmut,

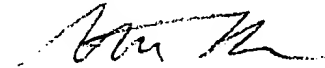
I would like to let you know of some new developments at Raya Systems since we last spoke.

In order to allow Todd to immediately concentrate on Camit S 2.5, I hired a senior programmer to take over the project management of Diabcare. Todd is still involved in the project because he knows the source code, but the transfer of day-to-day responsibilities is nearly complete and the project manager should start reporting directly to you in a few weeks. His name is Jim Blum, and he has 16 years of experience in software project management and applications programming.

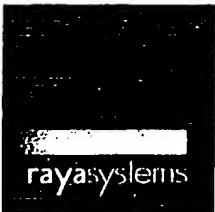
Beginning July 1, I am hiring an administrative assistant and technical writer who speaks both English and German. I hope to improve our communications by having someone always available to write status reports and translate them to German. We also need to start on the Camit 2.5 and Diabcare documentation. I assure you that everyone on the Boehringer Mannheim projects is working hard to get the job done. Many times we have felt so pressed for time that we have not kept you adequately informed. I recognize that for our work together to continue, we must improve the communications. The increased staff on BM projects should make a significant difference.

The American Diabetes Association has invited me to give a 25 minute presentation in one of the scientific sessions of the ADA conference in San Antonio. I am speaking in place of David Rodbard on Monday, June 22. The title of my presentation is "New Technology for Diabetes Education." We are showing a new product there and holding a press conference as well. Will you be able to come? 25 minutes is a long time for a presentation, and I could have time to discuss Camit.

Sincerely,



Steve Brown



Raya Systems, Inc.  
2570 West El Camino Real  
Suite 309  
Mountain View, CA 94040  
phone: (415) 949-3933  
fax: (415) 949-3935

**Meeting June 1, 1992**

Introductions

- Steve Brown
- Todd Ramming
- Jim Blum
- Emanuel Bouyssounouse
- Gerard Lum
- Natalie Khatset
- Louise Novak
- Jim Wehner
- Patty Scheurkogel

Raya Systems status

- Boehringer Mannheim
- Novo Nordisk
- NIH
- Nintendo

Organization

- Current: BM & NN
- Future: Research, Development, Sales, Finance, Project Management
- New position: sales director?
- New position: Nintendo producer
- New position: administrative support / technical writer

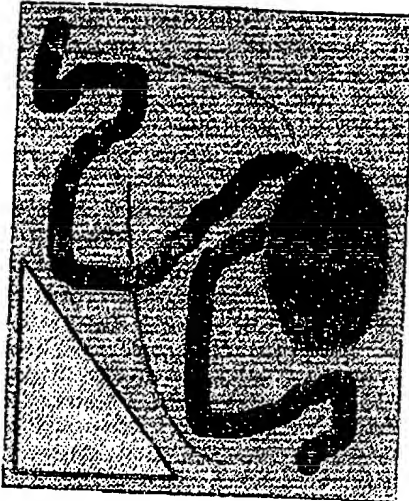
Administrative issues

- Phones
- Supplies
- Support person
- Benefits

06/02/1992 11:59 FROM

TO 14155490933

P.01



## FAX TRANSMITTAL

Jay Clark  
12434 82nd Ave. NE  
Kirkland, WA 98034  
TEL (206) 820-1057  
FAX (206) 820-1245

DATE 6/2/92 FAX (415) 949-3935

TO Raya Systems, Inc.  
Attn: Steve Brown

MESSAGE Steve, here is a revised version  
of the work agreement. I changed  
wording in the Definitions and Ownership  
sections in order to clarify that Raya owns  
the .EXE and all game-specific source code  
while I retain ownership of the libraries.  
If you don't call back, I'll assume the agreement is  
acceptable, sign it, and give it to Louise.

Pages to follow: 2

*Jay*

## Work-Made-for-Hire Agreement

### I. Introduction

This is a work made for hire agreement in which Jay Clark (Developer) agrees to provide software development services as an independent contractor to Raya Systems, Inc. (Raya). As consideration for all the duties of Developer herein, Raya shall pay Developer according to the payment schedule set forth in the document attached to this contract, which is incorporated by reference herein.

### II. Definitions

A. "Program" shall mean the computer program described in the document attached to this contract, which is hereby incorporated by reference. Program also includes all source code files necessary to compile the computer program. Source code files are text files containing C, C++, or assembler programming language constructs.

B. "Software Development Tools" shall mean all compilers, interpreters, linkers, routines, subroutines, and other programs that are used by Developer to develop the program specified in this contract, including routines and object code libraries developed by Developer.

### III. Duties

Developer shall create a computer program and related documentation (program) for Raya as per the specifications set forth in the document attached to this contract, which is incorporated by reference herein.

### IV. Ownership

Program is a work made for hire. Raya shall be considered the author of Program under the U.S. Copyright laws. The Program shall be the exclusive property of Raya.

Consistent with Developer's recognition of Raya's complete ownership rights in Program, Developer agrees not to use Program or any part of it, except for the material described in Section VII of this agreement, for the benefit of any party other than Raya.

Software Development Tools purchased or developed by Developer shall remain the property of Developer.

Raya is granted the exclusive right to use and modify any of the Developer's Software Development Tools for the sole purpose of modifying and compiling the Program. Raya cannot distribute any Software Development Tools to other parties without written approval from Developer.

**V. Completion Date**

Developer agrees to complete all work as per the schedule set forth in the document attached to this contract, which is hereby incorporated by reference herein. This agreement shall terminate upon completion of the work as per the attached schedule and specifications.

**VI. Trade Secrets**

Developer understands that Raya considers all programming to be a trade secret belonging to Raya. Developer, therefore, will neither divulge nor discuss with third parties matter relating to programs on which Developer is working or any other programs belonging to Raya without written permission of Raya. In addition, Developer agrees to sign, upon request, any reasonable nondisclosure agreements relating to any aspect of Raya's business. These obligations are perpetual and shall survive any termination of this agreement. Developer acknowledges that the payments earned as per the attached schedule are adequate consideration for all his duties under this agreement, including those in paragraph VI.

Upon publication of Program, Developer shall be free to include Program in his portfolio for demonstration.

**VII. Mediation and Arbitration**

If any dispute arises under the terms of this agreement the parties agree to select a mutually agreeable, neutral third party to help them mediate it. If the mediation is unsuccessful, the parties agree that the dispute shall be decided by binding arbitration under the rules issued by the American Arbitration Association. The decision of the arbitrator shall be final. Costs and fees (other than attorneys' fees) associated with the mediation or arbitration shall be shared equally by the parties. Each party shall be responsible for his or her Attorneys' fees associated with arbitration.

**VII. General Provisions**

A. Developer may neither subcontract nor hire persons to aid in the programming work without the prior written consent of Raya, not to be unreasonably withheld.

B. Any modifications to this agreement must be in writing and signed by both parties.

C. Developer is a subcontractor to Raya and not an employee.

\_\_\_\_\_  
Steve Brown  
President, Raya Systems, Inc.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Jay Clark

\_\_\_\_\_  
Date





SCULPTURED · SOFTWARE · INC.

June 8, 1992

Mr. Steve Brown  
President  
Raya Systems, Inc.  
2570 West El Camino Real, Suite 309  
Mountain View, CA 94040

Dear Steve:

I have enjoyed working with you on the Captain Novolin project for children with diabetes, and I look forward to working with you on more health related educational video games to be published by Raya Systems. Our development team enjoys the idea of finally creating something that can directly help kids.

As one of the most active developers of games for the Super Nintendo Entertainment System, Sculptured Software is currently doing major entertainment industry contracts for Acclaim, Lucasfilm, Parker Brothers, and Nintendo directly.

Some of our recent Super Nintendo titles are:

- Super WWF Wrestlemania (#1 selling Nintendo title this year)
- Roger Clemens MVP Baseball
- The Simpsons
- Super Star Wars
- Monopoly
- Clue
- NCAA Basketball (chosen to be published by Nintendo themselves)

We turn away dozens of game contracts each month, but we are particularly motivated to work with you on your projects because they are for a good cause, and they give us some diversity from our other projects. Frankly, we see Captain Novolin as the tip of a major iceberg.

Sincerely,

George C. Metos  
President  
Sculptured Software, Inc.

GCM/kep

June 16, 1992

Dr. Norbert Jersch  
Patient Systems  
Boehringer Mannheim GmbH  
Sandhoferstr. 116  
6800 Mannheim 31

Via fax: (011 49 621) 759 4179

Dear Norbert,

To follow is the timeline that Todd and I have been working from since it was agreed upon in Budapest on March 14 and confirmed later that month.

I hope to continue development on this schedule, but I am very concerned that commitments are being made about demonstrations, evaluations and product launch without my knowledge. There is virtually nothing we can do for June 25 because we have the ADA in San Antonio. We have promised to send an updated version of Diabcare the following week.

I have added experienced staff to the Diabcare project since the Budapest meeting. Everyone on the project is very committed and working overtime to get the job done. It is not a trivial program but is complex and full-blown networking database and analysis software with many special considerations to accommodate many different needs and perspectives.

The key problem since the beginning of Diabcare which continues today is that Raya Systems has the responsibility to develop the software, but no authority to make decisions about it. The result is that we often find ourselves stuck and the progress is slower than it could be. This is not true with our other projects.

Raya Systems has already sold 10,000 copies of our educational Nintendo software and it will be in every U.S. hospital by the end of the year. With this broad customer base using computers for diabetes we are in an ideal position to step into data management. We hope to have the chance to work with you to integrate our educational products with data management and outcome evaluation programs such as Camit and Diabcare as a means to achieve the first diabetes data management with wide acceptance and use.

[REDACTED]

Sincerely,



Steve Brown



Raya Systems, Inc.  
2570 West El Camino Real  
Suite 309  
Mountain View, CA 94040  
phone: (415) 949-3933  
fax: (415) 949-3935

June 18, 1992

Dr. Klaus Piwernetz  
DIABCARE Office  
Ledererstr. 10  
D-8000 München 2

Via Fax: (011 49 89) 298375

Dear Klaus:

To recap what we discussed on the phone today, I want to avoid at all costs delaying the already tight timeline of the complex Diabcare program, but I agree with you that it is also critical to support the simpler tools which will allow you to continue your work with the basic information sheet.

As a solution to our predicament I have hired a contractor who is an expert in dBase applications to provide you with the conversion tools to ensure that your Basic Information Sheet database (the "flat file") can be transferred back and forth with Diabcare.

We provided you with a conversion program in April for converting the flat file to Diabcare. Please be as explicit as possible in identifying the conversion errors, because it is often difficult for us to recognize the errors without your expertise. As you suggested, we are checking the conversion algorithm for eyes and feet complications. If there are any other errors, please let me know as soon as possible.

In order to test the conversion utilities it is essential that we get the following items as soon as possible:

1. Your 4000 record flat file. Using dummy data alone we can not duplicate the errors.
2. A Diabcare database suitable for testing the conversion from Diabcare to flat file.
3. An updated description of the fields in the flat file you are using



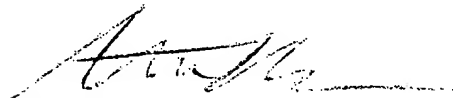
Raya Systems, Inc.  
2570 West El Camino Real  
Suite 309  
Mountain View, CA 94040  
phone: (415) 949-3933  
fax: (415) 949-3935

Attached to this fax, I am sending you the description of the table mapping from the flat file to Diabcare. Please note the conversion algorithms, because when the conversion is not direct, we are open to errors that are difficult to trace. I must make sure that our understandings are consistent.

If we get the information from you, I should be able to send you an updated conversion program in Oslo, hopefully with the conversion working in both directions. I have delayed my flight to the San Antonio until Friday. You can contact me during the ADA at the following address:

Marriott Rivercenter  
101 Bowie Street  
San Antonio, Texas 78205  
phone (512) 223 1000  
fax (512) 223 6239

Sincerely,



Steve Brown  
President  
Raya Systems

CC: Norbert Jersch. Boehringer Mannheim



Raya Systems, Inc.  
2570 West El Camino Real  
Suite 309  
Mountain View, CA 94040  
phone: (415) 949-3933  
fax: (415) 949-3935

LES, MORRISON & RINKER  
LAWYERS  
ACCOUNTING DEPT. 3011  
P.O. BOX 34936  
SEATTLE, WASHINGTON 98124-1936  
(206) 623-3427

# 2392

EXHIBIT P  
PAGE 1 OF 8

FEDERAL ID NO. 91-0574243

July 28, 1992  
Invoice 59796 Page 1

RAYA SYSTEMS  
2570 W EL CAMINO REAL  
SUITE 309  
MT VIEW CA 94040

Our File #C6228-009 For Services Through 06/22/92  
Corporate

06/16/92 Telephone call to C.Godward regarding  
Corp.records;Review documents;organize file.  
KMM 3.80 hrs.

06/17/92 Organize/set up files;Review contracts;  
Preparation of indexes;Telephone call from  
C.Godward.  
KMM 3.40 hrs.

06/18/92 Review documents;Organize files;Office conference  
with JVD.  
KMM 2.20 hrs.

Fees for legal services.....\$ 611.00

Total fees and costs.....\$ 611.00

Our File #C6228-006 For Services Through 06/22/92  
Diabetes - Contract

06/10/92 Reply to objections to our proposed contract.  
RB 3.00 hrs.

06/11/92 NNAS contract revisions & Preparation of Letter to  
Novo regarding sam.  
RB 4.30 hrs.

06/12/92 Dictate Letter to Novo regarding  
contract;Telephone call S.Brown;Revise Letter per  
Brown;Review Letter to Mikkelson  
RB 2.00 hrs.

06/12/92 ReDraft & fax Letter to Mikkelson  
RB 3.50 hrs.

OLDS, MORRISON & RINKER  
LAWYERS  
ACCOUNTING DEPT. 3011  
P.O. BOX 34936  
SEATTLE, WASHINGTON 98124-1936  
(206) 623-3427  
FEDERAL ID NO. 91-0574243

RAYA SYSTEMS

July 28, 1992  
Invoice 59796 Page 2

06/13/92	Review contract pursuant to Telephone conference with S.Brown;Revise attachments;Review of old contract RB	2.00 hrs.	
06/13/92	Review Letter to NNAS to ensure incorp of concerns;Drafting of Letter to Brown; RB	2.00 hrs.	
06/13/92	Drafting of second letter to NNAS;fax letters & contract RB	1.60 hrs.	
06/15/92	Telephone call from Steve regarding pricing clauses & other final details of NNAS; RB	1.30 hrs.	
06/15/92	Preparation of Letter to S.Mikkelson;Review attachment C RB	1.00 hrs.	
06/17/92	Office conference ADM regarding NNAS contract;Review Correspondence & modifications w/NNAS;Memorandum to file & ADM RB	.60 hrs.	
06/22/92	Review proposed NNAS contract. DSO	.20 hrs.	
06/22/92	Review proposed ammend to NPPI contract;Review orig NPPI Agreement & compare; Office conference DSO regarding same RB	.60 hrs.	
	Fees for legal services.....	\$	2007.00
	<u>ADVANCED COSTS</u>		
	Postage/Telecopy	\$	17.97
	Telephone Charges	\$	13.33
	Photocopies	\$	9.00
	Total Costs.....	\$	40.30
	Total fees and costs.....	\$	2047.30

OLES, MORRISON & RINKER  
LAWYERS  
ACCOUNTING DEPT. 3011  
P.O. BOX 34936  
SEATTLE, WASHINGTON 98124-1936  
(206) 623-3427

FEDERAL ID NO. 91-0574243

RAYA SYSTEMS

July 28, 1992  
Invoice 59796 Page 3

Our File #C6228-010  
Intellectual Property

For Services Through 06/22/92

ADVANCED COSTS

Photocopies	\$	10.80
Total Costs.....	\$	10.80
Total fees and costs.....	\$	10.80

Our File #C6228-001  
Miscellaneous

For Services Through 06/22/92

05/26/92	Review Letter from former counsel of S.Brown regarding release of files. RB	.50 hrs.
05/27/92	Telephone calls to Cooley; Preparation of Letter to Cooley regarding file release. RB	.80 hrs.
06/01/92	Review billing Memorandum. RB	.20 hrs.
06/11/92	Revise Medical Director Agreement per Letter. JVD	1.00 hrs.
06/13/92	Reorganize Raya file according to new projects. RB	.50 hrs.
06/15/92	Office conference with RB regarding case background, record organization & maintenance of files. KMM	2.10 hrs.
06/15/92	Office conference KMM regarding file organization RB	.30 hrs.

OLES, MORRISON & RINKER  
LAWYERS  
ACCOUNTING DEPT. 3011  
P.O. BOX 34936  
SEATTLE, WASHINGTON 98124-1936  
(206) 623-3427

FEDERAL ID NO. 91-0574243

July 28, 1992  
Invoice 59796 Page 4

RAYA SYSTEMS

06/16/92 Telephone conference with DSO regarding new  
confidentiality contract; Office conference ADM re  
same  
RB .20 hrs.

06/17/92 Drafting of employment confidentiality contract.  
RB 1.40 hrs.

06/17/92 Check Calif. statute regarding limits on employee  
confidentiality Agreements.  
ABL .90 hrs.

06/18/92 Review employee confidentiality draft.  
ADM .90 hrs.

Fees for legal services.....\$ 747.50

ADVANCED COSTS

Postage/Telecopy	\$ 157.99
Telephone Charges	\$ 195.51
Photocopies	\$ 216.20
Word Processing	\$ 418.00
Lexis Computer Usage	\$ 13.23

Total Costs.....\$ 1010.93

Total fees and costs.....\$ 1758.43

Our File #C6228-007  
Nintendo - Contract

For Services Through 06/22/92

06/01/92 Work on addendum to Nintendo contract.  
RB .60 hrs.

Fees for legal services.....\$ 54.00

ADVANCED COSTS

Photocopies	\$ 6.20
-------------	---------



OLES, MORRISON & RINKER  
LAWYERS  
ACCOUNTING DEPT. 3011  
P.O. BOX 34936  
SEATTLE, WASHINGTON 98124-1936  
(206) 623-3427

FEDERAL ID NO. 91-0574243

RAYA SYSTEMS

July 28, 1992  
Invoice # 59796 Page 5

Total Costs.....\$ 6.20

Total fees and costs.....\$ 60.20

Our File #C6228-002 For Services Through 06/22/92  
PCSL (Verlag) Contract

06/01/92 Work on new Europe game.  
RB .80 hrs.

06/08/92 Review draft contract for AIDS game;Suggest  
revisions.  
DSO .30 hrs.

06/08/92 Review Letter of understanding faxed from  
Steve;Telephone calls to Steve regarding contract  
regarding AIDS  
RB 1.50 hrs.

06/08/92 dictate Letter for Steve's Review  
RB 1.50 hrs.

06/09/92 Preparation of Letter to S.Brown regarding DSO's  
comments on AIDS contract;  
RB 1.80 hrs.

06/09/92 Telephone calls to/from Steve Brown;Drafting of  
Letter  
RB 1.80 hrs.

Fees for legal services.....\$ 720.00

Total fees and costs.....\$ 720.00

July 28, 1992  
Invoice 59796 Page 6

For Services Through 06/22/92

PAYMENTS RECEIVED ON OR AFTER STATEMENT DATE WILL NOT BE REFLECTED ON THIS INVOICE  
NET 30-THEREAFTER INTEREST CHARGES AT 12% PER ANNUM ON THE UNPAID BALANCE

OLES, MORRISON & RINKER  
LAWYERS  
ACCOUNTING DEPT. 3011  
P.O. BOX 34936  
SEATTLE, WASHINGTON 98124-1936  
(206) 623-3427

FEDERAL ID NO. 91-0574243

RAYA SYSTEMS

July 28, 1992  
Invoice 59796 Page 7

06/01/92 Review & Revise medical director Agreement as per  
Steve's instructions.  
RB 1.80 hrs.

06/10/92 Letter to Dr. Taylor.  
RB 1.70 hrs.

Fees for legal services.....\$ 1074.50

ADVANCED COSTS

Photocopies \$ 5.20

Total Costs.....\$ 5.20

Total fees and costs.....\$ 1079.70

PLEASE REMIT TOTAL BALANCE DUE.....\$ 6287.43

This invoice may not include expense items for which we have not yet been billed

RAYA SYSTEMS, INC.  
2570 W. EL CAMINO REAL #309  
MOUNTAIN VIEW, CA 94040

BANK OF AMERICA NT & SA  
SAN ANTONIO BRANCH 0448  
P.O. BOX 340  
MOUNTAIN VIEW, CA 94042  
11-35/1210

2392

17 Aug 92

*Pay to the  
Order of*

Oles, Morrison & Rinker

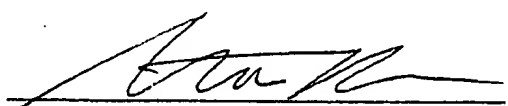
\$ \*\*\*\*\*6,287.43

ix Thousand Two Hundred Eighty-Seven and 43/100\*\*\*\*\*

*Dollars*

Oles, Morrison & Rinker  
Lawyers  
Accounting Dept. 3011  
P.O. Box 34936  
Seattle, Washington 98124-1936

emo



⑈002392⑈ ⑆121000358⑆ 04482⑈ 15097⑈

⑈0000628743⑈



6500 WILSHIRE BLVD SUITE 1960  
LOS ANGELES, CALIFORNIA 90048  
TEL 213 852 9600  
FAX 213 852 4747

June 25, 1992

Mr. Steve Brown  
Raya Systems  
2570 West El Camino #309  
Mountain View, California 94040

Dear Mr. Brown,

As we discussed, Emerson Brooks and Associates, Incorporated agrees to charge a flat fee of Five Thousand (\$5,000.00) dollars, for the placement of Mr. Jack Thornton only.

Emerson Brooks also agrees to a Thirty (30) calendar day unconditional guarantee, and a Thirty-one (31) to Ninety (90) calendar day guarantee, pro-rated on a daily basis, for Mr. Thornton.

Terms of payment shall be One-third (1/3) net Thirty (30) days, One-third (1/3) net Sixty (60) days, and (1/3) net Ninety (90) days from Mr. Thornton's start date.

Should you have any questions, please feel free to contact me at your convenience.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Jeffrey P. Brunner', is written over a horizontal line.

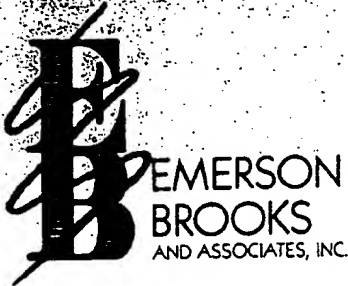
Jeffrey P. Brunner  
Software Engineering Division

Agreed: \_\_\_\_\_

Mr. Steve Brown

Date: \_\_\_\_\_

JB/lc



# 2393

6500 WILSHIRE BLVD SUITE 1960  
LOS ANGELES, CALIFORNIA 90048  
TEL 213 852 9600  
FAX 213 852 4747

DATE: June 30, 1992

INVOICE # 2493  
Client # 1321

Raya Systems  
2570 West El Camino Suite 309  
Mountain View, California 94040

Attn: Mr. Steve Brown  
Software Manager

---

FOR SERVICES RENDERED IN THE PLACEMENT OF: Mr. Jack Thornton

START DATE: <sup>July 23</sup>  
~~July 1, 1992~~

Standard Fee	\$16,500.00
Less Discount	11,500.00-
Less Second Invoice	1,666.67-
Less Third Invoice	1,666.66-
	-----
Net Due:	\$1,666.67

Aug 25

TERMS OF PAYMENT ARE NET DUE FIVE THOUSAND (\$5,000.00) DOLLARS. THE FIRST PAYMENT OF ONE THOUSAND, SIX HUNDRED, SIXTY-SIX DOLLARS AND SIXTY-SEVEN CENTS (\$1,666.67) IS DUE ON OR BEFORE ~~JULY 30, 1992~~. THE SECOND PAYMENT OF ONE THOUSAND, SIX HUNDRED, SIXTY-SIX DOLLARS AND SIXTY-SEVEN CENTS (\$1,666.67) IS DUE ON OR BEFORE ~~AUGUST 29, 1992~~. THE THIRD PAYMENT OF ONE THOUSAND, SIX HUNDRED, SIXTY-SIX DOLLARS AND SIXTY-SIX CENTS (\$1,666.66) IS DUE ON OR BEFORE ~~SEPTEMBER 28, 1992~~. GUARANTEE EXPIRES ON SEPTEMBER 28, 1992.

THIS IS THE FIRST OF THREE (3) INVOICES.

sep 23

oct 73

RAYA SYSTEMS, INC.  
2570 W. EL CAMINO REAL #309  
MOUNTAIN VIEW, CA 94040

BANK OF AMERICA NT & SA  
SAN ANTONIO BRANCH 0448  
P.O. BOX 340  
MOUNTAIN VIEW, CA 94042  
11-35/1210

2393

17 Aug 92

Pay to the  
Order of Emerson Brooks and Associates,

\$\*\*\*\*1,666.67

One Thousand Six Hundred Sixty-Six and 67/100\*\*\*\*\*

Dollars

Emerson Brooks and Associates,  
Inc.  
6500 Wilshire Blvd Suite 1960  
Los Angeles, CA 90048

82692000008810324

memo

002393 121000358 04482 15097

0000166667

**BUSINESS SERVICES**  
**PAYROLL SERVICE**

COMPANY NUMBER	PAYROLL NUMBER	HOME DEPT. NUMBER
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
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PAYROLL PERIOD  
ENDING DATE

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10/1/53	100	20

RAYA SYSTEMS INC

6-30-92

-26-92 1 SF 1992

EXHIBIT Q  
PAGE 4 OF 5

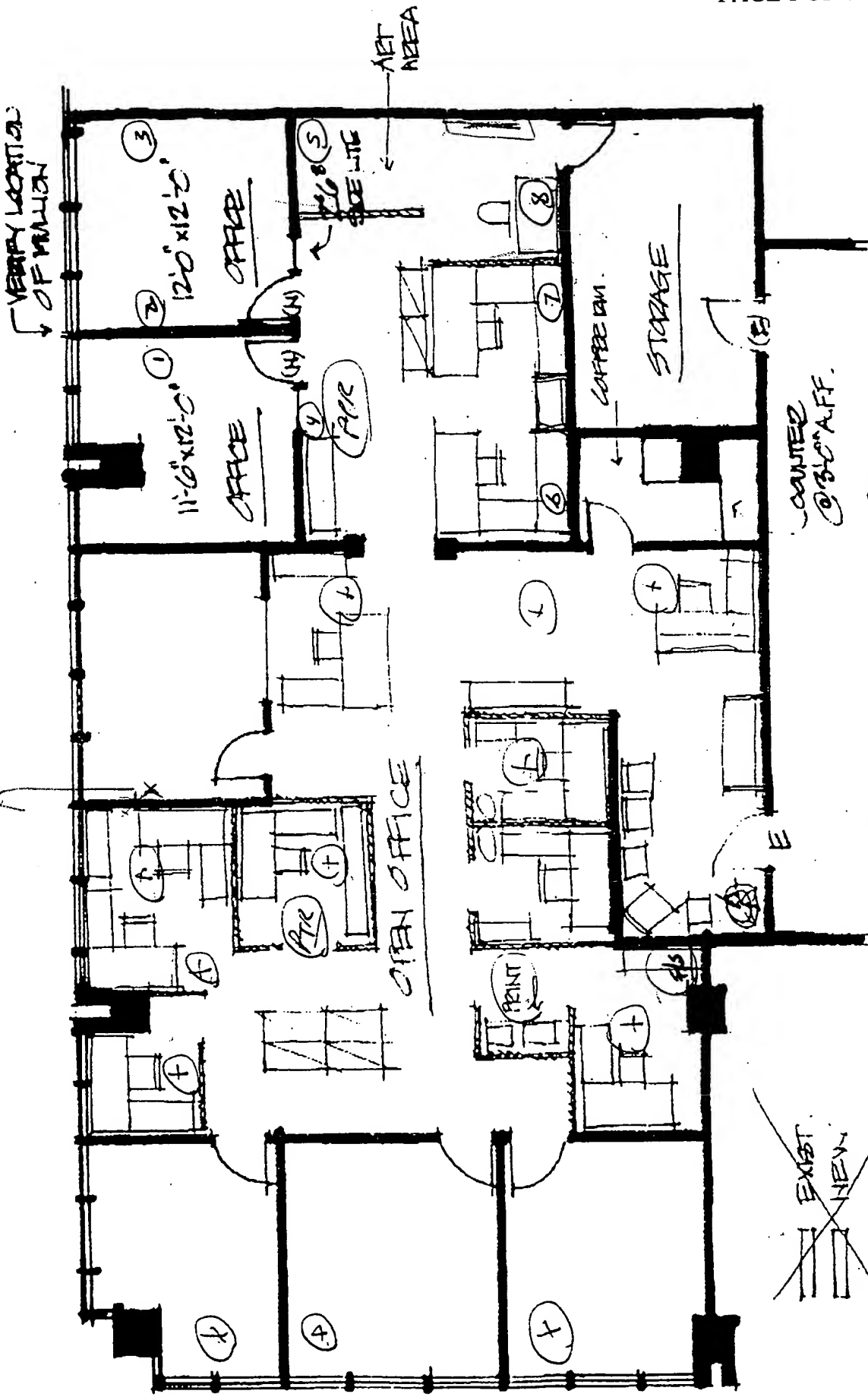


## Employee Master Information 1992

Employee	1992 Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Amo, Clarice													
Baker, Aaron													
Blum, Jim													
Bouyssemaoise, Emanuel													
Brown, Steve													
Gaxiola, Gina													
Gerneny, Beth													
George, Jeff													
Hall, Hope													
Khatset, Natalie													
Kobayashi, Hael													
Lum, Gerard													
Montemar, Beth													
Novak, Louise													
Porter, Cheri													
Ramming, Todd													
Renshaw, Cheryl													
Roathe, Lane													
Scheurkogel, Patty													
Thornston, Jack													
Wehner, Jim													
Williams, Art													

EXISTING  
NEW

Apply to all partitions  
Bk for 3 partitions



PROPOSED EXPANSION FOR:  
DATA SYSTEMS @ SAN ANTONIO OFFICE CENTER  
10'-0" x 12'-0" 12'-0" x 12'-0"

MOVABLE  
PARTITIONS

EXIST.  
NEW

NOTE: VERIFY ELEC/PHONE  
EXIST. OR INSTALL AS NEW  
RELOCATE LIGHTING & HVAC  
AS REQUIRED.

BUILD-OUT  
WALL TO  
CREATE  
12" DEEP  
ARCHWAY

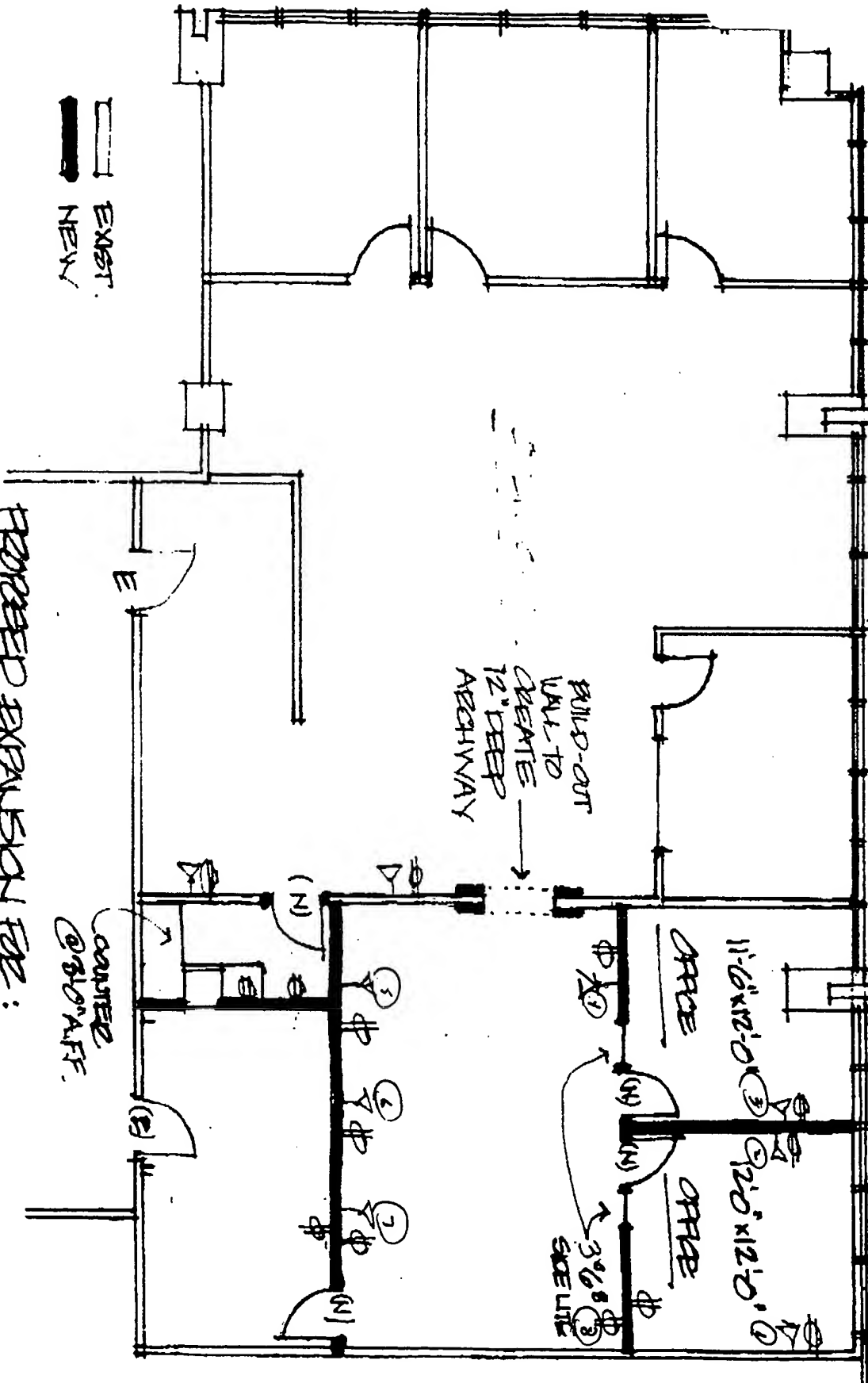
NEW ARCHWAY  
AS SHOWN

VERIFY LOCATION  
OF WALL

3 1/2" x 8" x 3"  
SIDE LITE

COUNTER  
@ 810" A.F.F.

FOR REEF EXHAUST FAN TOP:  
PAPA SYSTEMS @ SAN ANTONIO OFFICE CENTER  
10" = 1'-0" 6/12/92



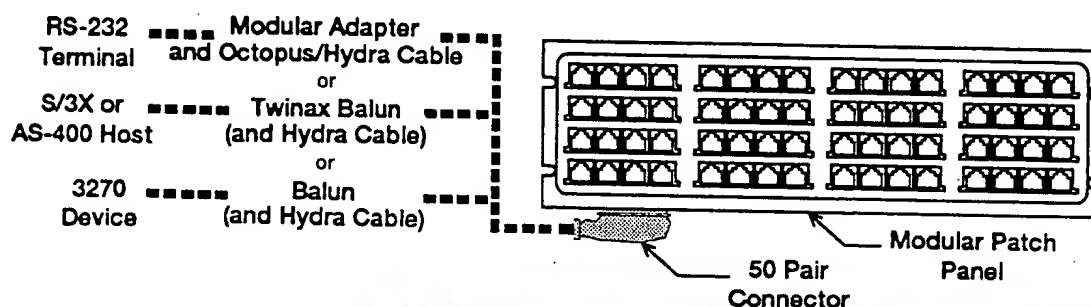
# PC Board Distribution Patch Panel

Using standard telecommunication components, the panel converts a 25-pair (50-pin) connector into a cluster of modular RJ11 or RJ45 jacks. Each jack is numbered to correspond to host or terminal ports. Each of the 25 twisted pair cables can contain either 3270-type data terminals from a single controller

(up to 24 terminals per cable), twinax data links (up to eight per cable), or RS232C ports (up to eight per cable).

Localized cross-connecting and circuit rearrangements are accomplished by patching modular line cords from one jack to another. The result is increased flexibility and a reduction of costly downtime by providing a bypass in the event of equipment failure.

## NEVADA WESTERN PC Board Distribution Patch Panel



### Specifications

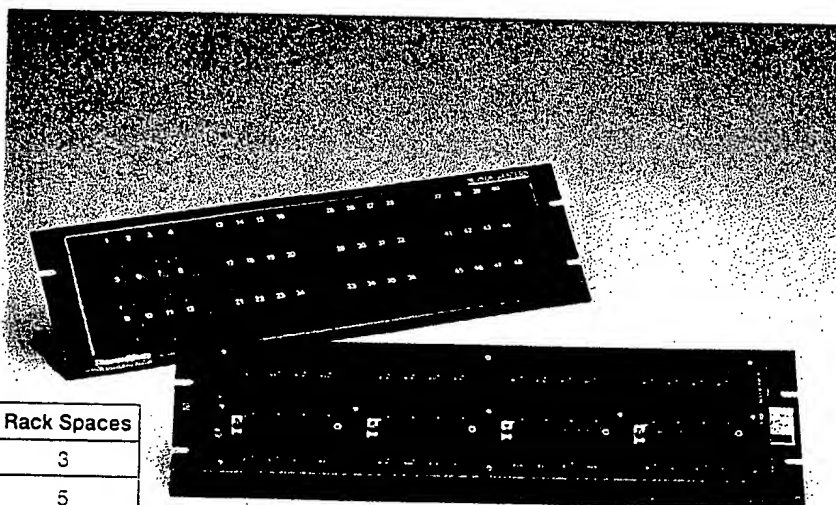
Dimensions: 24-port: 19" w, 1 1/2" d, 1 3/4" h  
48-port: 19" w, 1 1/2" d, 5 1/4" h  
96-port: 19" w, 1 1/2" d, 8 3/4" h

Data rate: 4 Mbps

Environment: 3X74 — distribution  
RS232C — distribution  
Twinax — distribution  
Voice/PBX — distribution

### Catalog Number

Wiring Series	No. Ports	Catalog Number	Rack Spaces
1000-2 wire	48	023-1000-48-2P	3
	96	023-1000-96-2P	5
1000-4 wire	48	023-1000-48-4P	3
	96	023-1000-96-4P	5
1000-6 wire	48	023-1000-48-6P	3
	96	023-1000-96-6P	5
1300-4 wire	24	023-1300-24-4P	1
2000-8 wire	48	023-2000-48-8P	3
	96	023-2000-96-8P	5
8000-8 wire	48	023-8000-48-8P	3
	96	023-8000-96-8P	5



For ordering or other information,  
please call our Regional Sales Offices:

Western Region (800) 828-9287  
Midwest Region (800) 247-5370  
Eastern Region (800) 542-6859

### NEVADA WESTERN

A Subsidiary of Thomas & Betts Corporation  
615 North Tasman Drive  
Sunnyvale, CA 94089-1950  
(408) 734-2700

**Thomas & Betts**

JUL 06 '92 12:56 HANSEN BROS CONSTR 408 7357109



Construction Specialties, Inc., 2273 De La-Cruz Blvd., Santa Clara, CA 95050, License No: 435395, Phone: 408/727-2777, FAX: 408/727-1161

July 7, 1992

Raya Systems  
2570 West ElCamino Real # 309  
Mountain View, CA 94040

Attn.: Ms. Louise Novak

Reg.: Tenant Improvement.

Dear Ms. Novak,

Thank you for the opportunity to give the following price quotations. Based on your instructions and your 1 pc. drawings:

1. Build new walls per owners plan.
2. Install 15 new electrical power outlets and provide 10 wall cut and box for telephone, per drawing. Provide and install six new 2x4 light fixtures and wall switching (8 total ). Change two existing single switches to 3 way switches.
3. Provide three new doors and frames. Hardware passage lever.
4. Provide and install two 5.0 x 6.8 windows aluminum frame, tempered glass per code.
5. Paint (standard) new office areas. Sand and refinish entry door.
6. Demo existing carpet and install new carpet and rubber base to match carpet in suite 309.
7. Fabricate new reception counter; L-shape with two colors and design on front panel to simulate arch in new opening.
8. Clean up & supervision.

TOTAL PROJECT COST ..... \$ 18,789.00

N.I.C.: Plans, permits, fees. Moving equipment and furniture

All work to be done to all state and local codes.

Ed Iglesias  
Estimator/Project Manager

MARKETING DEPARTMENT  
NORVESCO CARE DIVISION  
TELEFAX + 45 42 98 58 00

EXHIBIT S  
PAGE 1 OF 3  
NC  
DK  
TELEPHONE

Page: 1 of: 1

---

To: Steve Brown  
Raya Systems

Fax No: 009 1 415 949 3935

From: Liz Dempsey Becker

Date: July 2, 1992

cc.: SKHa

---

Dear Steve:

Congratulations on the overwhelming success of Captain Novolin! Obviously it was the major news from the ADA this year. I hope you are as pleased with the feedback as is Novo Nordisk.

As mentioned to you at the conference, we are unable to plan similar exposure at EASD because we are launching a new product and focusing on our R&D projects. However, with those affiliates that take Captain NovoCare, we are urging them to do a PR campaign as was done in the US. We are collecting all the media clippings so that we can use them to "sell" the program to the affiliates.

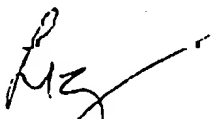
We will only have one "play station" at our stand. Please let me know the technical specs for the hardware you believe necessary at the booth for the pc version. We must either ship the equipment by August 15 or try and rent it in Czechoslovakia (if they have it!).

For your info, all of the 7 affiliates are reviewing their packages at the moment and will return to us ASAP. I have given Louise their names so that she can contact them to move the process.

I will be moving the project along while Susanne is away so call or fax anytime.

Congratulations again!

Liz



Louise Sent fax of  
recommended hardware for  
convention 7/2/92

**INTL. MARKETING DEPARTMENT**  
**DIABETES CARE DIVISION**  
**TELEFAX + 45 42 98 58 00**

**NOVO NORDISK A/S**  
**DK 2880 BAGSVÆRD**  
**TELEPHONE + 45 4444 8888**

Page: 1 of: 1

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To: Steve Brown  
Raya Systems

Fax No: 009 1 415 949 39 35

From: Liz Dempsey Becker

Date: July 10, 1992

cc.: SKHa

---

Dear Steve:

Thanks for your fax and your suggestions for EASD. However, I think it is necessary for you to attend for many reasons. The interested doctors will most likely want to hear about how/why the game was developed and the "tooting" it has been through. I'm referring here to the presentation you made at ADA. They may also have heard something about it at ADA.

In addition, a number of affiliate marketing people will be either working on the stand or attending the congress. They will be interested in meeting you to talk generally about versions for their countries as well as want to know more about how/when the game could be moved on to Nintendo. While I agree, working on the stand may be a bit boring, we really think for the above reasons that you should attend.

I hope this does not create any problems.

*Liz*

Liz

.: Liz Dempsey Becker  
Novo Nordisk, Copenhagen  
011- 45-44-44-2131

From: Steve Brown  
Raya Systems  
001-415-949-3935

Date: July 14, 1992

Pages: 1

---

Dear Liz,

I would be happy to meet with the affiliate marketing people and demonstrate Captain NovoCare to doctors at the booth, but I would not be able to work at the booth full-time, because I will need to go to some other meetings. I also may be participating in one of the presentations (still tentative). If you need someone to be there all of the time, I suggest that either two (2) people from Raya be there or that a Novo Nordisk person learn how to demonstrate the game.

I don't mind working on the stand, but I have some other obligations as well.

Sincerely,

Steve Brown



P.S. I am still waiting for a response to the contract. Erik says (and it is fine with me) that we should keep North America and The Rest of the World separate, so it needs a slight modification.

P.P.S. I heard that Susanne was confused about Conversions, Modifications, and Sequels. Those are commonly understood terms in the computer game world, but I will try to make some better definitions if she can let me know where the confusion lies.

Swiss Air 1042 rt 14 day min stay 6 days; no rooms available  
Delta 1080 rt



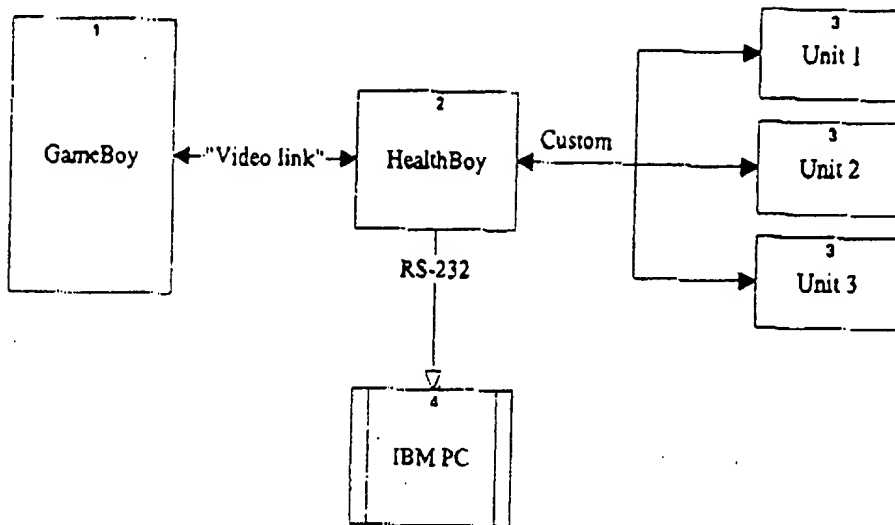
rayasystems

HealthBoy Project

TopChart

Thursday, August 13, 1992

11:46 AM



CONFIDENTIAL

HealthBoy features:

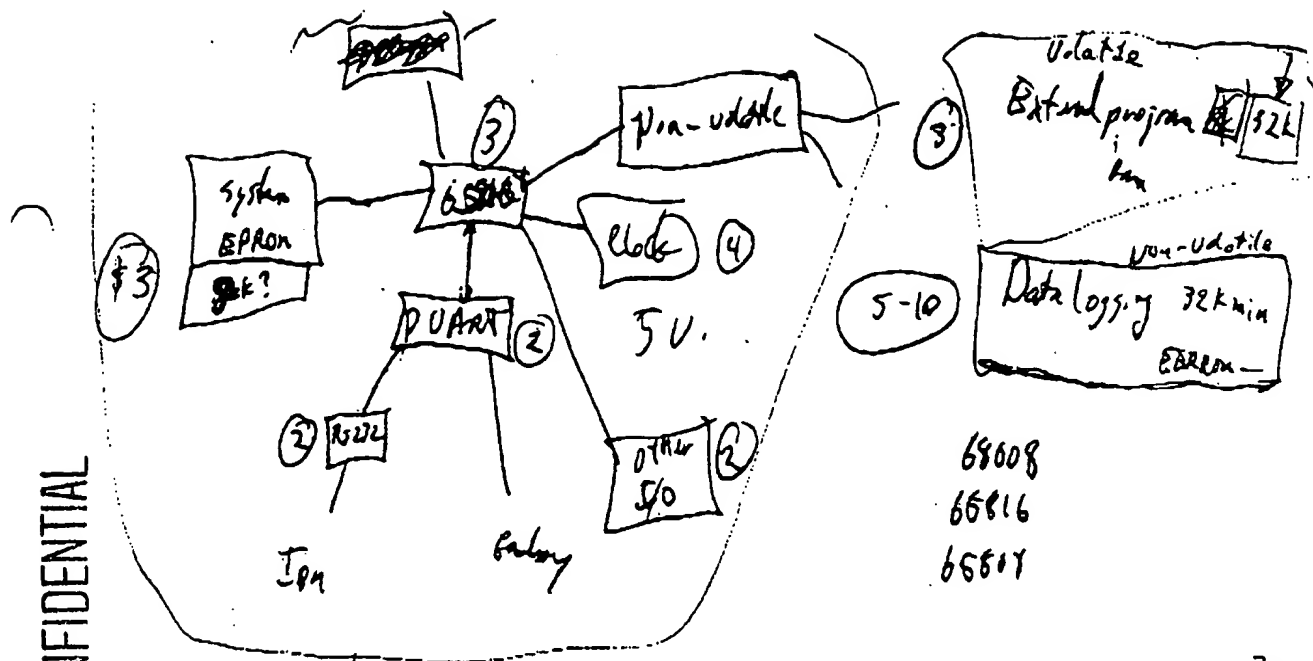
- ☐ Communicate to GameBoy via serial "Video-Link" (multi-player) cable
- ☐ Communicate to multiple external devices (e.g. diabetes blood-sugar meter) via custom hookup
- ☐ Dump data to external computers (e.g. IBM PC) via RS-232 (9-pin connector)
- ☐ Clock/Calendar capability for time/date stamp of samples
- ☐ Internal battery backed-up RAM for storage of samples
- ☐ Low-power microprocessor
- ☐ Input connectors designed to be "user stupid"/hard to damage
- ☐ GameBoy cartridges for each external device for display of data

Hardware wish list:

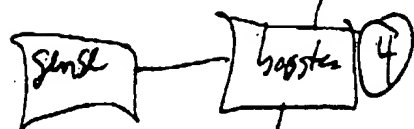
- ☐ Microprocessor with multiple interrupt levels
- ☐ Hardware-driven communications with GameBoy with buffer
- ☐ Automatic RS-232 buffer
- ☐ Hardware-driven communications with external devices with buffer
- ☐ Large amount of RAM for long-term storage of samples

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68008  
68816  
68801



~3-4.5

Linear Act Block

map standby 1mg

100

30 hrs ← 100 hrs

- 1) Full on
- 2) Standby
- 3) off

3 - AA - 3 A hr.

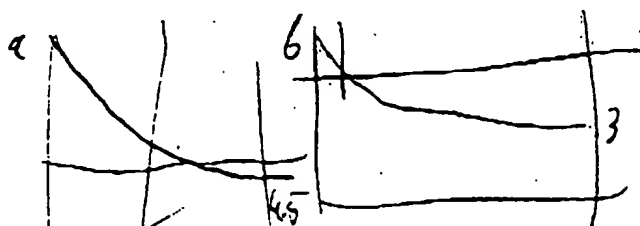
Use 6AA - 500mg - 5 hrs

management consulting??

\$3B<sup>6</sup>

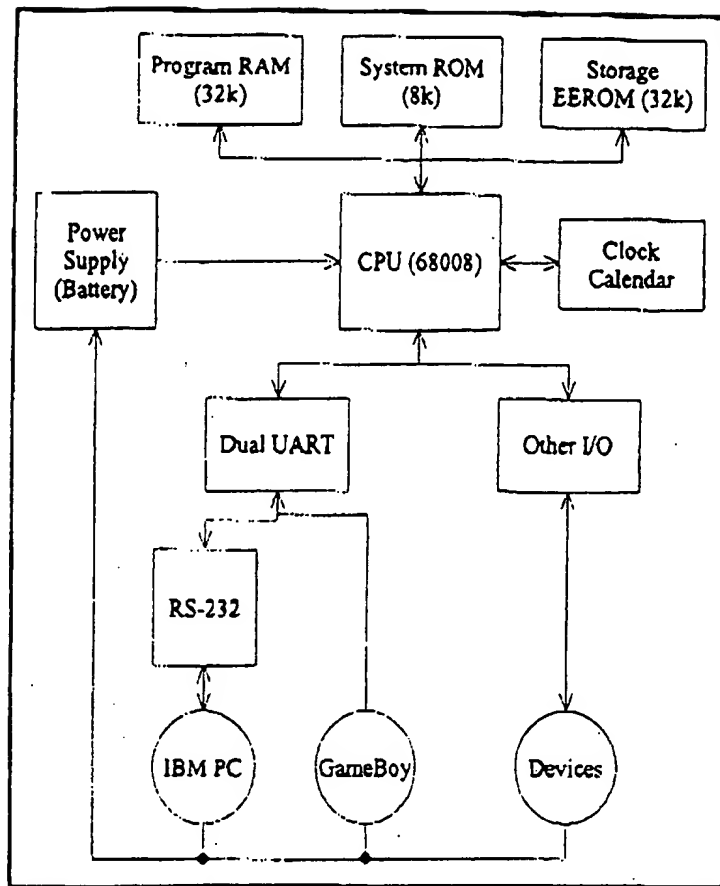
PCB ~ \$1

plastic tooling  
4 months  
maybe 6 months



- 1 - circuit design - 1 month design - \$50 hr
- 1 - PCB layout - 2 weeks; Electronics - had cost more \$30 hr
- 1 - prototype - 1 month

usually ~ \$1 unit



Development Cost (estimates)

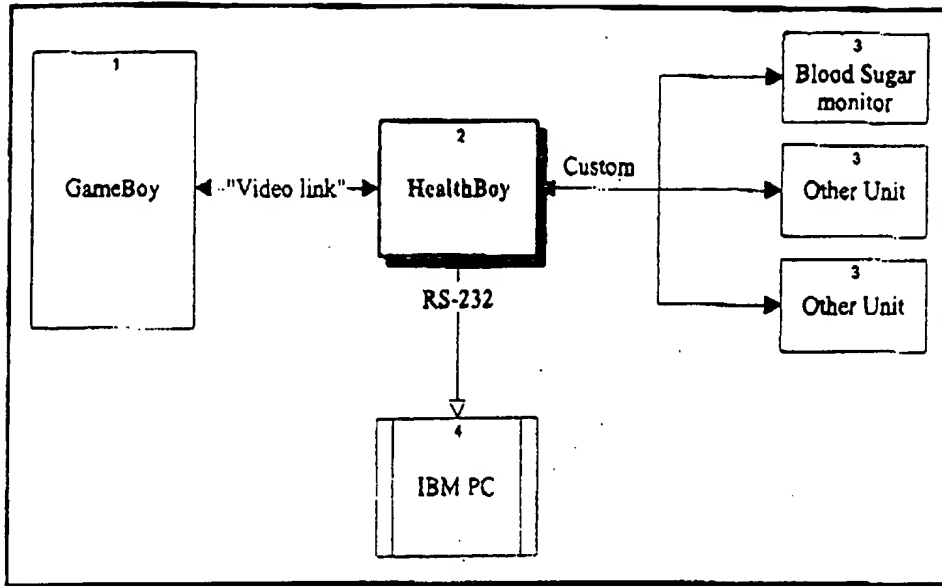
Description	Units	Unit type	Rate	% use	Brdn Rate	Cost
Hardware design/test	6	weeks	\$2,000.00	100%	100%	\$12,000.00
Hardware prototyping	4	weeks	\$800.00	100%	100%	\$3,200.00
Circuit board design	2	weeks	\$1,200.00	100%	100%	\$2,400.00
Plastic design & development	4	months				\$20,000.00
Software design	4	weeks	\$1,000.00	100%	125%	\$5,000.00
Software implement/test	6	weeks	\$1,000.00	100%	125%	\$7,500.00
Management	14	weeks	\$1,084.62	10%	125%	\$1,893.08
Clerical	14	weeks	\$538.46	5%	125%	\$471.16
Photocopy/Supplies	14	weeks	\$10.00	100%	100%	\$140.00
Telephone	14	weeks	\$10.00	100%	100%	\$140.00
Shipping						\$300.00
GameBoy Develop. system						\$13,000.00
IBM PC System						\$2,600.00
Estimated costs						\$68,549.23
Reserve (15%)						\$10,282.38
Total development budget						\$78,831.62

Note:

Another option is to build our own custom chip to perform most of the functions of the separate parts specified in the design.

Advantages:


Functional design / features



Basic hardware design

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rayasystems**CONFIDENTIAL**  
**Non-Disclosure Agreement**

This agreement is made to be effective the 13th day of August, 1992 by and between Craig Nelson and Raya Systems, Inc., 2570 West El Camino Real, Suite 309, Mountain View, CA 94040, hereinafter referred to as "PARTIES."

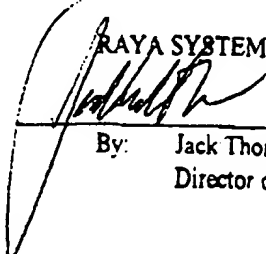
The "PARTIES" agree that, with respect to any confidential information disclosed by one PARTY to the other, both PARTIES will apply and honor the mutual covenants and promises described below:

- (1) "Confidential Information" shall be any and all information which is in fact confidential and proprietary to the disclosing PARTY and which the disclosing PARTY designates as confidential at the time such disclosure is made;
- (2) The non-disclosing PARTY shall not disclose or cause to be disclosed, in whole or in part, any such Confidential Information to any third party without the prior written consent of the disclosing PARTY, except where:
  - (a) at the time of disclosure, the Information is publicly known, or was already known (as evidenced by documents) by the non-disclosing PARTY, or
  - (b) after disclosure to a PARTY, such information becomes publicly known through no fault of the PARTIES, or
  - (c) disclosure is required by law or governmental agency or any subdivision thereof, or
  - (d) seven (7) years have elapsed from the date upon which disclosure is made;
- (3) In the event that either of the PARTIES breaches this agreement, the breaching PARTY shall be liable for any and all losses resulting from said breach which are incurred by the non-breaching PARTY.

8/13/92  
Date

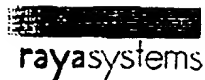
  
By: Craig Nelson

8/13/92  
Date

RAYA SYSTEMS, INC.  
  
By: Jack Thornton  
Director of Product Development

**CONFIDENTIAL**

## F A X L E T T E R



Raya Systems, Inc.  
2570 West El Camino Real, Suite 309, Mountain View, California 94040  
Phone (415) 949-3933 Fax (415) 949-3935

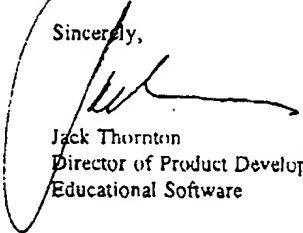
TO:	Richard T. Black
COMPANY:	Oles, Morrison & Rinker
FAX NUMBER:	(206) 682-6234
FROM:	Jack Thornton
DATE:	August 14, 1992
RE:	HealthBoy project - potential patent application
NUMBER OF PAGES:	7, including this one
CC:	Steve Brown

I have been instructed by Steve Brown to forward notes about the HealthBoy project to you for the purposes of a possible patent application. I met with a hardware engineer yesterday, and based on that information I have a very preliminary design of the central module with cost estimates. Included in this fax are my notes, the engineer's (Craig Nelson's) handwritten notes, and the non-disclosure agreement signed by Craig.

As more information is developed, I will be forwarding it to you.

If you have any questions, please feel free to give me a call.

Sincerely,

  
Jack Thornton  
Director of Product Development  
Educational Software

RECEIVED  
8:15 PM  
AUG 14 1992

OLES, MORRISON & RINKER

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CONFIDENTIAL

- Lower per-unit cost (estimated \$10 less per unit, depending on quantity manufactured at one time)
- Lower MSRP (by \$50 to \$80)
- Allow for addition of customized features (hardware assisted communications, etc) which increase usefulness and flexibility of the device

## Disadvantages:

- Increase development time from 3.5 months to 9.5 months (additional 6 months)
- Increase development cost by about \$60,000

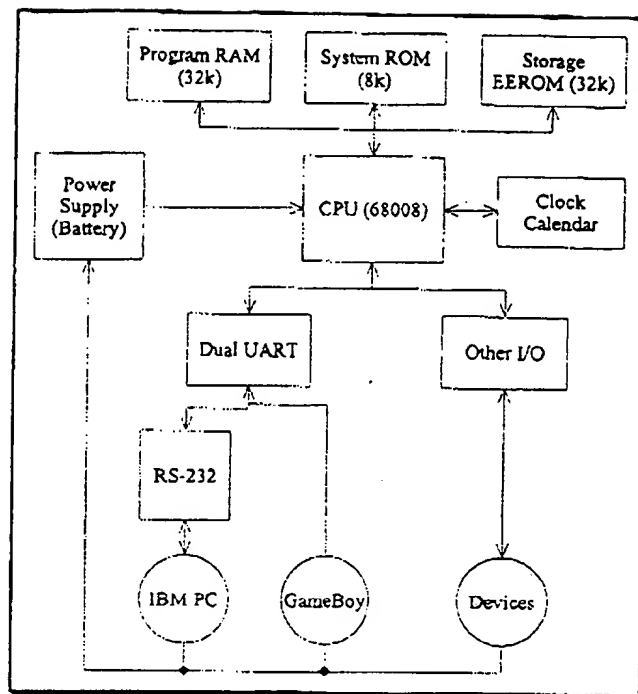
## Per-unit cost (estimates)

Description	Cost	
Hard costs (parts and connectors)	\$35.00	
Circuit board	\$1.00	
Plastic case	\$0.50	
Assembly	\$1.00	
Packaging (box, packing, instruction booklet)	\$1.50	
Total estimated per-unit cost	\$39.00	
MSRP range	\$195.00	\$312.00

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Development Cost (estimates)

Description	Units	Unit type	Rate	% use	Brdn Rate	Cost
Hardware design/test	6	weeks	\$2,000.00	100%	100%	\$12,000.00
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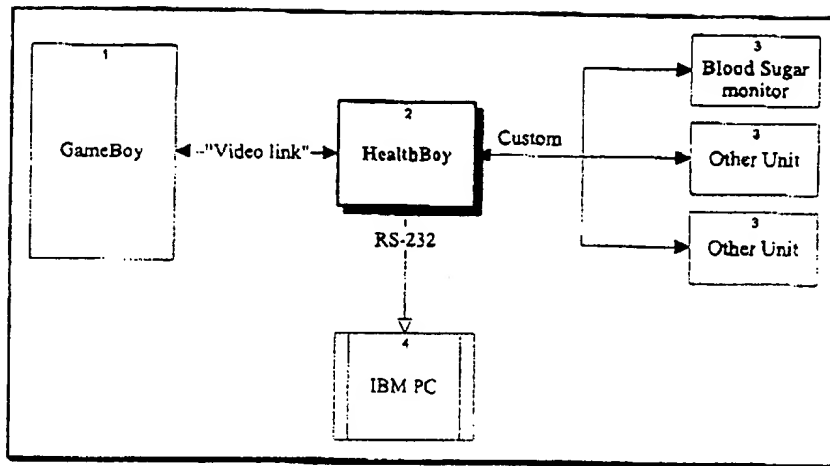
## Note:

Another option is to build our own custom chip to perform most of the functions of the separate parts specified in the design.

Advantages:



## Functional design / features




## Basic hardware design

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rayasystems**CONFIDENTIAL**  
**Non-Disclosure Agreement**

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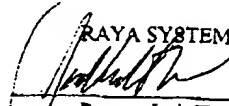
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  - (b) after disclosure to a PARTY, such information becomes publicly known through no fault of the PARTIES, or
  - (c) disclosure is required by law or governmental agency or any subdivision thereof, or
  - (d) seven (7) years have elapsed from the date upon which disclosure is made;
- (3) In the event that either of the PARTIES breaches this agreement, the breaching PARTY shall be liable for any and all losses resulting from said breach which are incurred by the non-breaching PARTY.

8/13/92  
Date

  
By: Craig Nelson

8/13/92  
Date

  
RAYA SYSTEMS, INC.  
By: Jack Thornton  
Director of Product Development

**CONFIDENTIAL**

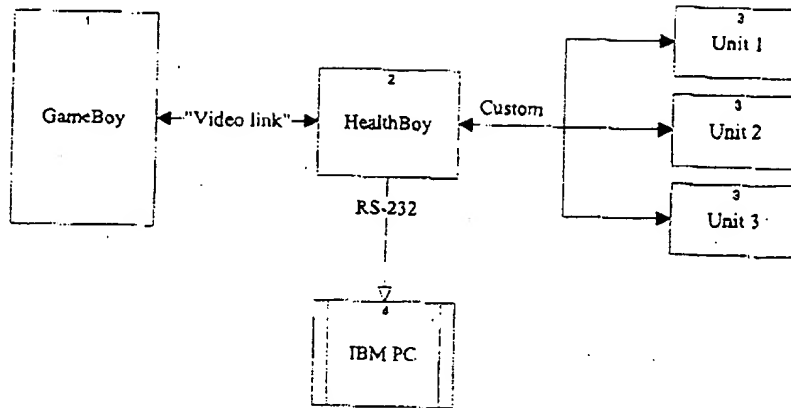
**rayasystems**

## HealthBoy Project

TopChart

Thursday, August 13, 1992

11:46 AM



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### HealthBoy features:

- ☐ Communicate to GameBoy via serial "Video-Link" (multi-player) cable
- ☐ Communicate to multiple external devices (e.g. diabetes blood-sugar meter) via custom hookup
- ☐ Dump data to external computers (e.g. IBM PC) via RS-232 (9-pin connector)
- ☐ Clock/Calendar capability for time/date stamp of samples
- ☐ Internal battery backed-up RAM for storage of samples
- ☐ Low-power microprocessor
- ☐ Input connectors designed to be "user stupid"/hard to damage
- ☐ GameBoy cartridges for each external device for display of data

### Hardware wish list:

- ☐ Microprocessor with multiple interrupt levels
- ☐ Hardware-driven communications with GameBoy with buffer
- ☐ Automatic RS-232 buffer
- ☐ Hardware-driven communications with external devices with buffer
- ☐ Large amount of RAM for long-term storage of samples

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Jack - Confidential 8/21/92  
(1/2)

The Healthway presentation went very well. We need to put together a complete Proposal with the following points:

- ① Prototype with off the shelf components, including modem
- ② Production model with custom chips and plastic
- ③ Software
- ④ Central server software - Data points to fax report conversion
- ⑤ Pilot Study with 100 Patients at a good medical

Confidential . (2/2)

I survived the product managers picking it apart, found some great ways for them to make money with it, and The VP of marketing has bought into it.

I'd like to meet first thing Monday morning to discuss it.

Steve.

PS. For now we can assume using an off the shelf meter - rather than an integrated one. After the pilot, this will be an option.

**OLES, MORRISON & RINKER**  
LAWYERS

3300 COLUMBIA CENTER  
701 FIFTH AVENUE  
SEATTLE, WASHINGTON 98104-7007  
(206) 623-3427  
TELECOPIER: (206) 662-6234

SETH W. MORRISON  
BRUCE T. RINKER  
DAVID C. STEWART  
SAM E. BAKER, JR.  
ARTHUR D. MCGARRY  
B. MICHAEL SCHESTOPOL  
THEODORE L. PREG  
WILLIAM G. JEFFERY  
ROBERT J. BURKE  
DAVID H. KARLEN

BRADLEY L. POWELL  
DOUGLAS S. OLES  
PETER N. RALSTON  
MICHELE M. SALES  
MARK F. O'DONNELL  
JOHN LUKJANOWICZ  
DAVID R. TRACHTENBERG  
JAMES F. NAGLE  
KRIS J. SUNDBERG

RICHARD T. BLACK  
TIM W. DORE  
MICHAEL M. FERRING  
HARLAN M. HATFIELD  
T. DANIEL HEFFERNAN  
EVALYN K. HODGES  
JON G. HONGLADAROM  
JOHN F. JENKEL

TRAEGER MACHETANZ  
GLENN R. NELSON  
TODD M. NELSON  
JOHN V. OHNSTAD, JR.  
BRIAN E. ONORATO  
J. CRAIG RUSK  
ROBERT W. SARGEANT

STUART G. OLES  
OF COUNSEL

GERALD DE GARMO  
(1903-1988)

September 3, 1992

VIA FAX

Mr. Stephen Brown  
Raya Systems, Inc.  
2570 West El Camino Real, Suite 309  
Mt. View, CA 94040

**RE: Patent Application**

Dear Steve:

As per your instructions, we have authorized Jim Anable to begin work on your application. He and his office should be contacting you frequently in the next several weeks, and it is important that you and Jack respond promptly to his questions to expedite the process.

Normally, it is optimal to do a patentability search in advance of the application to minimize the risk of denial. You have asked that the search be deferred until later so that you can meet your Sept. 23rd deadline and to avoid the extra cost. After the meeting, you might want to do a search so that you can amend the application (to the extent possible) to better avoid the prior art, and so maximize the odds of patentability. If you could afford to, it would be best to pay for the patentability search now so that it could be done while your application is being developed, and the results incorporated into the application before filing. However, because of cost considerations, I will assume you are willing to bear the risk of omitting or deferring a patentability search.

Please call if you have any questions. I will be at (509) 663-2225 from Friday until Tuesday.

Very truly yours,

OLES, MORRISON & RINKER

*Richard T. Black*

Richard T. Black

cc: Douglas S. Oles

OLES, MORRISON & RINKER  
LAWYERS

3300 COLUMBIA CENTER  
701 FIFTH AVENUE  
SEATTLE, WASHINGTON 98104-7082  
(206) 623-3427

TELECOPIER: (206) 682-6234

SETH W. MORRISON  
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DAVID C. STEWART  
SAM E. BAKER, JR.  
ARTHUR D. MCGARRY  
B. MICHAEL SCHESTOPOL  
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WILLIAM G. JEFFERY  
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TODD M. NELSON  
BRIAN E. ONORATO  
ROBERT W. SARGEANT

STUART G. OLES  
OF COUNSEL

GERALD DE GARMO  
(1903-1988)

September 15, 1992

James W. Anable, Esq.  
Christensen, O'Connor, Johnson & Kindness  
2800 Pacific First Center  
1420 Fifth Avenue  
Seattle, WA 98101

RE: Raya Systems, Inc.

Dear Jim:

Enclosed is Raya's check in the amount of \$6,000 as a retainer for your work on Raya's patent. Please forward a receipt to Raya.

Very truly yours,

OLES, MORRISON & RINKER



Richard T. Black

RTB/jd  
Enclosure  
cc: Douglas Oles, Esq.



2407

2 Sep 92

BANK OF AMERICA  
SAN ANTONIO BRANCH 0448  
P.O. BOX 340  
MOUNTAIN VIEW, CA 94042  
11-35/1210

RAYA SYSTEMS, INC.  
2570 W. EL CAMINO REAL #309  
MOUNTAIN VIEW, CA 94040

\$ \*\*\*\*6,000.00

Pay to the  
Order of

Christianson D'Conner

Dollars

Six Thousand and 00/100\*\*\*\*\*

Christiansen D'Conner



Patent Health Boy

memo

⑈002407⑈ ⑆121000358⑆ 01482⑈15097⑈



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service  
National Institutes of HealthNational Institute of Diabetes and  
Digestive and Kidney Diseases  
Bethesda, Maryland 20892

September 9, 1992

FILE COPY

Our Reference: 2 R44 DK44402-02

Stephen J. Brown  
President, Raya Systems, Inc.  
2570 West El Camino Real  
Suite 309  
Mountain View, CA 94040

Dear Mr. Brown:

We have begun an administrative review of the above referenced Phase II Small Business Innovation Research (SBIR) grant application in the event that it is selected for funding. As part of our administrative review, we have identified the following issues that must be addressed before any funding decision can be made.

- o Human Subjects Assurance
- o Confirmation of Direct and Indirect Cost Award Amounts
- o Update of Other Support
- o Anticipated Program Income
- o Waiver of Fee/Profit

For applications involving human subjects, Public Health Service policy requires prospective grantees to submit an assurance of compliance with protection of human subjects regulations. Since the research proposed in this application involves the use of human subjects, an Assurance must be submitted to and accepted by the Office for Protection from Research Risks (OPRR), NIH. OPRR will contact you concerning the procedure for obtaining the appropriate assurance.

Current SBIR Guidelines state that the total cost (direct plus indirect) of a Phase II award may not exceed \$500,000. Our preliminary review indicates that the estimated total cost is \$500,000. This is based on recommended direct costs of \$455,200 plus \$44,800 indirect costs. Indirect costs were calculated based on a salary/wage rate of 27%.

These figures are subject to adjustment pending final indirect cost negotiation within the \$500,000 limit. If an award is offered, the \$500,000 will be distributed evenly for the two budget periods. Please confirm your acceptance of this in your response letter.

- 2 -

Please provide updated Other Support information for the Principal Investigator and all other key personnel. This information should be shown in three groups: (1) all currently active research support; (2) all applications or proposals pending review or funding; and (3) applications and proposals planned or being prepared. Include all federal and non-federal grant and contract support and specifically identify SBIR projects. For each item, give the source of funding, identifying number, project title, name of principal investigator, hours per week on the project, annual direct costs, dates of the entire period of support and a brief description of the project. If any of these overlap, duplicate, or are being replaced or supplemented by the present application, delineate and justify the nature and extent of the scientific and budgetary overlaps or boundaries.

Public Health Service (PHS) policy requires applicants for PHS research grants to include in their grant applications an estimate of the amount and source of program income expected to be generated as a result of the project for which support is being sought. The specific policies that govern the treatment of program income under research grants are set forth in the Interim Update to the 10/01/90 edition of the PHS Grants Policy Statement. Please include a statement to this effect in your response letter.

Effective with SBIR grant awards with budget period start dates of July 1, 1992, and beyond, grantee organizations may request a reasonable fee or profit as part of the total amount of the SBIR award. That is, a fee or profit may be provided within the maximum amount allowed under the SBIR program, which is \$500,000 for Phase II grants. In your response letter, please include a statement declining or waiving this fee/profit, or a revised budget proposing inclusion of this fee/profit. Either response must be properly countersigned by your business official.

Once the above issues have been addressed satisfactorily, we will proceed with issuing a Notice of Grant Award for this project. However, please be aware that this letter does not take the place of the official award notice. Therefore, any expenditures or commitments made prior to receipt of a Notice of Grant Award, are at your own risk.

The signatures below identify the Institute staff administering this award. The Program Director should be contacted with respect to scientific and technical aspects of the award and the Grants Management Specialist should be contacted regarding business administration of the award and matters pertaining to PHS policies.

- 3 -

If you have any questions or if we may be of assistance, please contact us.

Sincerely,

*Charles A. Wells*

Charles A. Wells, Ph.D.  
Diabetes Research Prog. Director  
Diabetes Research Program, DPB  
Div. of Diabetes, Endocrinology  
and Metabolic Diseases  
Room 622 Westwood (301)496-7731

*Linda M. Stecklein*

Linda M. Stecklein  
Grants Management Officer  
Grants Management Branch  
Div. of Extramural Activities  
Room 649 Westwood (301)496-7467

September 10, 1992

Reference: 2 R44 DK444402-02

Ms. Linda Stecklein  
Grants Management Officer  
National Institute of Diabetes and Digestive and Kidney Diseases  
Westwood Building, Room 649  
Bethesda, MD 20892

Dear Ms. Stecklein:

With this letter I hope to address the questions raised in the administrative review and the budgetary concerns in the summary statement. Either Louise Novak, Patty Scheurkogel or I will follow up on each point to make sure we have provided the answers and documentation you need.

1. Budgetary Concerns in the Summary Statement. In response to the concerns in the summary statement of our Phase II Small Business Innovation Research grant, I am submitting a revised budget which addresses the issues raised. (Please find it attached to this document.)

The summary statement raised concerns that we had underestimated the amount of work to administer the proposed study. Raya Systems has grown since the original proposal, adding general administrative personnel so that researchers and project managers may more efficiently focus on their projects. Our original estimate of overhead costs did not include general office administration, and I have revised the budget to reflect our actual overhead costs. ~~(Patty Scheurkogel, our financial manager, will provide the documentation of our 1990, 1991 and 1992 year to date overhead costs.)~~

In the revised budget, we have reduced the number of subjects from 250 to 200, thus requiring fewer Nintendo sets and fewer lab tests. This reduction puts an additional burden on the researchers to insure that the measures are strong enough, but I am confident we can find a way to do that. Other savings occur because the price of the Super Nintendo Entertainment System has come down to \$100 from \$165 at the time of the proposal.



Raya Systems, Inc.  
2570 West El Camino Real  
Suite 309  
Mountain View, CA 94040  
phone: (415) 949-3933  
fax: (415) 949-3935

The summary statement suggests that money could be saved by using computers rather than Super Nintendo Entertainment Systems. It should be noted that this proposal tests an in-the-home intervention, and the Nintendo platform was chosen not only for its appeal to children and ease of use, but also because it costs significantly less than a computer. By choosing the Nintendo system, we can supply each subject with an inexpensive, familiar, and identical platform for the experiment. We are thus able to control otherwise significant variables such as familiarity with computers and differences in computer hardware.

Since this research depends on the video game being of the same style, quality and depth as video games from the entertainment industry, we have proposed to subcontract the programming of the game based on our design to a professional Nintendo developer that works primarily for the entertainment industry. Their bid of \$160,000 to program the game with the same quality and depth of other games in their portfolio such as "The Simpsons" and "Star Wars" is very reasonable, and it would cost us more to do the programming in house. Sculptured Software is able to make the bid because they can reuse tools they have developed for the entertainment industry for similar games. At Sculptured Software, there will be a project manager, programmer, artist, musician and game tester working on the project.

As indicated in the summary statement, the budgets for the consultants have been increased. After reconsidering the schedule, I have shifted some of the costs from the first year to the second year. Also, there has been a staff change for the development project manager. Jim Wehner has been replaced by Jeff George, an experienced game designer and project manager from the video game industry. (His resume is attached.)

2. Human Subjects Assurance. ~~Louise Novak will follow up with this next week.~~

3. Confirmation of Direct and Indirect Cost Award Amounts. As indicated in the revised budget, the direct and indirect cost amounts are as follows:

Project	Direct Costs	Indirect Costs	Total
Year	Requested	Requested	Cost
02	216,200	33,600	249,800
03	<u>190,900</u>	<u>51,000</u>	<u>241,900</u>
Total	407,100	84,600	491,700

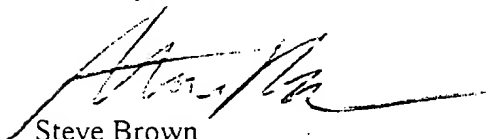
4. Update of Other Support. ~~Two grants pending review have been funded. Patty Scheurkogel will send the updated Other Support pages next week.~~

5. Anticipated Program Income. We do not anticipate program income for this project until the completion of the grant support.

6. Fee/Profit. In the revised budget, the total direct and indirect costs add up to \$491,700. We request a fee/profit of \$8300 so that total amount remains \$500,000.

I hope this letter addresses your concerns. If you have any questions, please don't hesitate to call me at (415) 949-3933. All of us at Raya Systems look forward to starting the project as soon as possible.

Sincerely,



Steve Brown  
President  
Raya Systems



Raya Systems, Inc.  
2570 West El Camino Real  
Suite 309  
Mountain View, CA 94040  
phone: (415) 949-3933  
fax: (415) 949-3935

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE

**NOTICE OF GRANT AWARD**

DATE ISSUED:

09/30/92

GRANT NUMBER: ZRG1 HUD-3 (4)

2 R44 DK44402-02

TYPE OF AWARD: SMALL BUSINESS INNOVATION RESEARCH PROG

AUTHORIZED BY: 42 USC 241 42 CFR PART 52 15 USC 638

TOTAL PROJECT PERIOD:

From 09/30/92 Through 09/29/94

AWARDED BY:

NAT INST OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Title of Project or Area of Training

COMPUTER GAME FOR DIABETES EDUCATION

Grantee Organization

RAYA SYSTEMS INCORPORATED  
2570 WEST EL CAMINO REAL  
SUITE 309  
MOUNTAIN VIEW, CA 94040

Principal Investigator/Program Director/Awardee

BROWN, STEPHEN J BS  
RAYA SYSTEMS INCORPORATED  
2570 WEST EL CAMINO REAL  
SUITE 309  
MOUNTAIN VIEW, CA 94040 12

**APPROVED BUDGET**

FOR BUDGET PERIOD 09/30/92 Through 09/29/93

Salaries and Wages ..... \$ 83,250

Fringe Benefits .....

Total Personnel Costs ..... \$ 83,250

Consultant Costs ..... 1,600

Equipment ..... 58,750

Supplies ..... 1,800

Travel - Domestic ..... 4,000

- Foreign .....

Patient Care - Inpatient .....

- Outpatient ..... 11,250

Alterations and Renovations .....

Consortium/Contractual Costs ..... 160,000

Other ..... 200

.....

Trainee Stipends .....

Trainee Tuition and Fees .....

Trainee Travel .....

TOTAL DIRECT COSTS → \$ 320,850

When PHS Prior Approval is required for rebudgeting, submit requests to Grants Management Official below.

**AWARD COMPUTATION**

DIRECT COSTS ..... \$ 320,850

INDIRECT COSTS ..... \$\* 41,625

SBIR FEE ..... 4,000

TOTAL ..... \$ 366,475

Less Unobligated Balance [Prior Period(s)] \$ 0

**AMOUNT OF THIS AWARD** → \$ 366,475

Base Dollars x Rate Percentage = Indirect Costs \$\*  
83,250 x 50.00 = 41,625

**SUPPORT RECOMMENDED FOR REMAINDER OF PROJECT PERIOD\*\***

Budget Total Direct Costs Stipends  
Period (Includes Stipends)

03 94,375

04 NONE

\*\* Subject to availability of funds and satisfactory progress.

**REMARKS**

AMOUNT AWARDED IS THE MAXIMUM ALLOWABLE CEILING TO BE REIMBURSED UNDER THIS GRANT.

#GRANTS MANAGEMENT: MRS. LINDA M. STECKLEIN (301) 496-7467

SEE ATTACHED FOR ANY ADDITIONAL TERMS AND CONDITIONS

TERMS OF ACCEPTANCE: By acceptance of funds awarded under this grant, the grantee acknowledges that it will comply with terms and conditions in the following:  
(1) Legislation cited above; (2) Regulations cited above; (3) Special provisions noted above under remarks or attached to this notice; (4) PHS Grants Policy Statement;  
(5) 45 CFR Part 74 or 92, as applicable. The above order of precedence shall prevail.

FY—Common Accounting Number

2-8425512

CRS/Entity Identification No.

1770207109A1

PHS List No./Object Class Code

/41.4B

Document Number

(08)R4DK44402B

PROGRAM OFFICIAL

*Charles A. Wells*  
CHARLES A. WELLS, PH.D.  
DIRECTOR, DIABETES RES PROG.  
DIV OF DIABETES, ENDOCRINOLOGY  
AND METABOLIC DISEASES, NIDDK

PHS Grants Management Official

*John R. Garthune*  
JOHN R. GARTHUNE  
ACTING CHIEF GRANTS MGMT OFFICER  
NAT INSTITUTE OF DIABETES AND  
DIGESTIVE AND KIDNEY DISEASES



TERMS AND CONDITIONS

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- NOTICE: UNDER GOVERNING REGULATIONS, FEDERAL FUNDS ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES SHALL NOT BE EXPENDED FOR AND INDIVIDUALS SHALL NOT BE ENROLLED IN RESEARCH INVOLVING HUMAN SUBJECTS, WITHOUT PRIOR APPROVAL BY THE OFFICE FOR PROTECTION FROM RESEARCH RISKS OF AN ASSURANCE TO COMPLY WITH THE REQUIREMENTS OF 45 CFR 46 TO PROTECT HUMAN RESEARCH SUBJECTS. THIS RESTRICTION APPLIES TO ALL PERFORMANCE SITES WITHOUT OPRR-APPROVED ASSURANCES, WHETHER DOMESTIC OR FOREIGN.
- THE BUDGET PERIOD BEGIN DATE OF THIS AWARD HAS BEEN EXPEDITED. HOWEVER, BASED ON AN UNUSUAL PROVISION IN THE FY 1992 NIH APPROPRIATION THAT MANDATED A DELAY IN OBLIGATING FY 1992 FUNDS, THE BEGIN DATE FOR THIS AWARD WILL BE SEPTEMBER 30, 1992.
- AMOUNT OF THIS AWARD IS THE MAXIMUM ALLOWABLE CEILING TO BE REIMBURSED UNDER THIS GRANT SUBJECT TO ADJUSTMENT BASED ON FINAL INDIRECT COST NEGOTIATIONS AND WITHIN THE \$500,000 LIMIT FOR THE -02 AND -03 BUDGET PERIODS.
- THE ESTIMATED "SUPPORT RECOMMENDED FOR REMAINDER OF PROJECT PERIOD" PLUS APPLICABLE INDIRECT COSTS (\$34,850) AND FEE/PROFIT (\$4,300), WHEN ADDED TO THE TOTAL AUTHORIZATION FOR THE -02 BUDGET PERIOD, MAY NOT EXCEED \$500,000.
- THE TOTAL FIXED FEE FOR THE SECOND COMPETITIVE SEGMENT OF THE PROJECT IS \$8,300 AND IS IN ADDITION TO ALLOWABLE DIRECT AND INDIRECT COSTS. \$4,000 ARE ALLOTTED FOR PAYMENT OF FIXED FEE FOR THE BUDGET PERIOD COVERED BY THIS NOTICE OF GRANT AWARD. ADDITIONAL FUNDS FOR THE REMAINDER OF THE TOTAL FIXED FEE ARE INTENDED TO BE ALLOTTED BY THE FUTURE NOTICE OF GRANT AWARD. UNLESS AND UNTIL SUCH FUTURE NOTICE OF GRANT AWARD IS ISSUED, THE GOVERNMENT WILL NOT BE OBLIGATED TO REIMBURSE THE GRANTEE ORGANIZATION FOR MORE THAN THE FUNDS PRESENTLY ALLOTTED FOR PAYMENT OF THE FIXED FEE. AN EQUITABLE ADJUSTMENT OF THE FEE WILL BE MADE IN THE EVENT THE GRANT IS TERMINATED OR FUTURE SUPPORT IS WITHHELD. THE FEE ALLOTTED UNDER THIS NOTICE OF GRANT AWARD SHOULD BE DRAWN DOWN FROM THE DHHS PAYMENT MANAGEMENT SYSTEM IN INCREMENTS BASED UPON THE PERCENTAGE OF COMPLETION OF THE PROJECT.
- NO AMOUNT PROVIDED FOR FEE OR PROFIT MAY BE REBUDGETED INTO DIRECT OR INDIRECT COSTS OR BE REIMBURSED FOR SUCH PURPOSE(S). FURTHER, UNOBLIGATED TOTAL COSTS (EXCLUDING FEE OR PROFIT) CREATE A PROPORTIONATE UNOBLIGATED AMOUNT FOR FEE OR PROFIT.
- GENERAL PROGRAM INCOME IS TO BE TREATED UNDER THE DEDUCTION ALTERNATIVE PER 45 CFR PART 74.715.

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2 R44 DK44402-02

- ALLOWABLE COSTS OF ACTIVITIES CONDUCTED BY FOR-PROFIT ORGANIZATIONS WILL BE DETERMINED BY APPLYING THE CONTRACT COST PRINCIPLES AND PROCEDURES SET FORTH IN PART 31 OF THE FEDERAL ACQUISITION REGULATIONS (FAR). HOWEVER, INDEPENDENT RESEARCH AND DEVELOPMENT COSTS (INCLUDING THE INDIRECT COSTS ALLOCABLE TO THEM) ARE UNALLOWABLE.
- TITLE TO EQUIPMENT ACQUIRED OR FABRICATED UNDER THIS GRANT SHALL VEST UPON ACQUISITION IN THE FEDERAL GOVERNMENT AND MUST BE ACCOUNTED FOR AS OUTLINED IN PART 45 OF THE FEDERAL ACQUISITION REGULATIONS (FAR). THE GRANTEE IS REQUIRED TO REPORT ALL PURCHASES OF EQUIPMENT WITH A UNIT COST OF \$500 OR MORE AND HAVING A USEFUL LIFE OF MORE THAN TWO YEARS. SUCH PURCHASES SHOULD BE REPORTED IN THE ANNUAL INVENTORY (DUE OCTOBER 15TH OF EACH YEAR) ON HHS FORM 565 OR EQUIVALENT DOCUMENT TO THE PROPERTY OFFICE LISTED BELOW:

RESEARCH CONTRACTS PROPERTY SECTION  
PERSONAL PROPERTY BRANCH  
NATIONAL INSTITUTES OF HEALTH  
BUILDING 13, ROOM 2E-65D  
BETHESDA, MD 20892  
TELEPHONE: (301) 496-6467

- PRIOR APPROVAL FROM THE AWARDING OFFICE IS REQUIRED FOR THE FOLLOWING ACTIONS:
  - CHANGE IN SCOPE OR OBJECTIVES
  - CHANGE IN PRINCIPAL INVESTIGATOR OR OTHER KEY PERSONNEL IDENTIFIED ON THE NOTICE OF GRANT AWARD.
  - ACTIVITIES OR EXPENDITURES RESTRICTED ON THE GRANT AWARD
  - CHANGE OF GRANTEE INSTITUTION/SUCCESSOR IN INTEREST/ RECIPIENT INSTITUTION NAME CHANGE
  - TRANSFERRING SUBSTANTIVE PROGRAMMATIC WORK TO A THIRD PARTY
  - CARRYOVER OF UNOBLIGATED FUNDS FROM ONE BUDGET PERIOD TO ANOTHER WITHIN AN APPROVED PROJECT PERIOD
  - EXTENSIONS OF THE BUDGET OR PROJECT PERIOD
  - PURCHASE OF EQUIPMENT COSTING MORE THAN \$25,000 PER UNIT
  - ALTERATIONS AND RENOVATIONS EXCEEDING \$25,000 IN A BUDGET PERIOD
  - PATIENT CARE COSTS WHERE THE NEED HAS NOT PREVIOUSLY BEEN APPROVED BY PHS AND/OR WHEN THE GRANTEE DESIRES TO REBUDGET FUNDS OUT OF THE PATIENT CARE CATEGORY
  - PREAWARD COSTS INCURRED MORE THAN 90 DAYS PRIOR TO THE EFFECTIVE DATE OF ANY NEW OR COMPETING CONTINUATION AWARD

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- TRANSFERRING MANAGEMENT SERVICES TO A THIRD PARTY WHICH EXCEED \$25,000
- CONSULTANT FEES WHEN ARRANGEMENT CONSTITUTES TRANSFER OF SUBSTANTIVE PROGRAMMATIC WORK TO A THIRD PARTY
- RETROACTIVE PRIOR APPROVAL

SUCH PRIOR APPROVAL SHOULD BE REQUESTED IN A LETTER SIGNED BY THE PRINCIPAL INVESTIGATOR AND A BUSINESS OFFICIAL OF THE GRANTEE INSTITUTION, SHOULD BE ADDRESSED TO THE GRANTS MANAGEMENT CONTACT IDENTIFIED ON THE NOTICE OF GRANT AWARD, AND SHOULD INCLUDE AN EXPLANATION AND JUSTIFICATION FOR THE ACTION(S). THE ABOVE IS AN ABBREVIATED LIST AND DOES NOT INCLUDE ALL ACTIONS WHICH REQUIRE PRIOR APPROVAL. IF THERE ARE ANY QUESTIONS AS TO WHETHER AN ACTION REQUIRES PRIOR APPROVAL OR NOT, CONTACT THE GRANTS MANAGEMENT REPRESENTATIVE.

O'CONNOR  
JOHNSON  
KINDNESS

PATENT, TRADEMARK AND OTHER  
INTELLECTUAL PROPERTY MATTERS

FAX: (206) 224-0779  
TELEX: 493802J  
CABLE: PATENTABLE

## FACSIMILE COVER SHEET

DATE: October 2, 1992

TO: Steve Brown/Jack Thornton

Raya Systems, Inc.

FACSIMILE NUMBER: (415) 949-3935

RE: Patent Application

OUR REFERENCE: RAYA-1-6631

YOUR REFERENCE: \_\_\_\_\_

FROM: James W. Anable, Esq.

(Facsimile No. (206) 224-0779 - Panafax Groups 1, 2 & 3)

### MESSAGE:

Please review and contact me. I am out of the office this morning but expect to return by noon. I will await your call.

Enclosures: Patent Application (DRAFT) and drawings (DRAFT)

\*\*\* The information contained in this facsimile message is privileged and confidential information intended only for the use of the recipient named above. If the reader of this message is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, any distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone and return the original message to us at the above address by mail. \*\*\*

We have 34 pages to send, including this sheet. If any pages need to be retransmitted, please call (206) 682-8100, Ext. \_\_\_\_\_, within 15 minutes.

This document was transmitted at \_\_\_\_\_:\_\_\_\_\_ m.

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## **MODULAR MICROPROCESSOR-BASED HEALTH MONITORING SYSTEM**

### **Field of the Invention**

This invention relates to administering and monitoring personal healthcare. More specifically, this invention relates to self-care health monitoring arrangements that enable a patient or other user to gather data important to a health management program and, if desired or necessary, easily provide that data to a healthcare professional.

### **Background of the Invention**

Controlling or curing conditions of ill health generally involves both establishing a therapeutic program and monitoring the progress of the afflicted person. Based on that progress, decisions can be made as to altering therapy to achieve a cure or maintain the affliction or condition at a controlled level. Successfully treating certain health conditions calls for rather frequent monitoring and a relatively high degree of patient participation. For example, in order to establish and maintain a regimen for successful diabetes care, a diabetic should monitor his or her blood glucose level and record that information along with the date and time at which the monitoring took place. Since diet, exercise, and medication all affect blood glucose levels, a diabetic often must record data relating to those items of information along with blood glucose level so that the diabetic may more closely monitor his or her condition and, in addition, can provide information of value to

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the healthcare provider in determining both progress of the patient and detecting any need to change the patient's therapy program.

Advances in the field of electronics over the past several years have brought about significant changes in medical diagnostic and monitoring equipment, including arrangements for self-care. With respect to the control and monitoring of diabetes, relatively inexpensive and relatively easy-to-use blood glucose monitoring systems have become available that provide reliable information that allows a diabetic and his or her healthcare professional to establish, monitor and adjust a treatment plan (diet, exercise, and medication). More specifically, microprocessor-based blood glucose monitoring systems are being marketed which sense the glucose level of a blood sample that is applied to a reagent-impregnated region of a test strip that is inserted in the glucose monitor. When the monitoring sequence is complete, the blood glucose level is displayed by, for example, a liquid crystal display (LCD) unit.

Typically, currently available self-care blood glucose monitoring units include a calendar/clock circuit and a memory circuit that allows a number of blood glucose test results to be stored along with the date and time at which the monitoring occurred. The stored test results (blood glucose level and associated time and date) can be sequentially recalled for review by the blood glucose monitor user or a health professional by sequentially actuating a push button or other control provided on the monitor. In some commercially available devices, the average of the blood glucose results that are stored in the monitor (or the average of the results for a predetermined period of time, e.g., fourteen days) also is displayed during the recall sequence. Further, some self-care blood glucose monitors allow the user to tag the test result with an "event code" that can be used to organize the test results into categories. For example, a user might use a specific event code to identify test results obtained at a particular times of the day, a different

event code to identify a blood glucose reading obtained after a period of exercise, two additional event codes to identify blood glucose readings taken during hypoglycemia symptoms and hyperglycemia symptoms, etc. When event codes are provided and used, the event code typically is displayed with each recalled blood glucose test result.

Microprocessor-based blood glucose monitoring systems have advantages other than the capability of obtaining reliable blood glucose test results and storing a number of the results for later recall and review. By using low power microprocessor and memory circuits and powering the units with small, high capacity batteries (e.g., a single alkaline battery), extremely compact and light designs have been achieved that allow taking the blood glucose monitoring system to work, school, or anywhere else the user might go with people encountered by the user not becoming aware of the monitoring system. In addition, most microprocessor-based self-care blood glucose monitoring systems have a memory capacity that allows the system to be programmed by the manufacturer so that the monitor displays a sequence of instructions during any necessary calibration or system tests and during the blood glucose test sequence itself. In addition, the system monitors various system conditions during a blood glucose test (e.g., whether a test strip is properly inserted in the monitor and whether a sufficient amount of blood has been applied to the reagent impregnated portion of the strip) and if an error is detected generates an appropriate display (e.g., "retest"). A data port may be provided that allows test results stored in the memory of the microprocessor-based blood glucose monitoring system to be transferred to a data port (e.g., RS-232 connection) of a personal computer or other such device for subsequent analysis.

Microprocessor-based blood glucose monitoring systems are a significant advance over previously available self-care systems such as those requiring a diabetic to apply a blood sample to reagent activated portions of a test strip; wipe the blood sample from the

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test strip after a predetermined period of time; and, after a second predetermined period of time, determine blood glucose level by comparing the color of the reagent activated regions of the test strip with a color chart supplied by the test strip manufacturer. However, several drawbacks and disadvantages exist, thus leaving several areas in which improvements would be of benefit both to the user and the healthcare professional. For example, establishing and maintaining diabetic healthcare often requires the diabetic to record additional data pertaining to medication, food intake, and exercise. However, the event codes of currently available microprocessor blood glucose monitoring systems do not allow the user of the system to tag and track blood glucose test results on a sufficiently accurate quantitative basis. For example, it would only be possible for the user to use the available event codes to classify stored blood glucose readings to indicate blood glucose tests taken immediately after a heavy meal and to identify blood glucose test results obtained after normal and light meals. This method of recording information not only requires subjective judgment by the system user, but will not suffice in a situation in which successfully controlling the user's diabetes requires the recording and tracking of relatively accurate information relating to food intake, exercise, or medication (e.g., insulin dosage). An otherwise significant advantage of currently available blood glucose monitoring systems is lost when blood glucose test results must be recorded and tracked with quantitative information relating to medication, food intake, or exercise. Specifically, the system user must record the required information along with a time and date tagged blood glucose test result by, for example, writing the information in a log book.

The use of event codes to establish subcategories of blood glucose test results has an additional disadvantage or drawback. In particular, although alphanumeric display devices are typically used in currently available microprocessor-based blood glucose



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monitoring systems, the display units are limited to a single line of information having on the order of six characters. Moreover, since the systems include no provision for the user to enter alphanumeric information, any event codes that are used must be indicated on the display in a generic manner, e.g., displayed as "EVENT 1", "EVENT 2", etc. This limitation makes the system more difficult to use because the diabetic must either memorize his or her assignment of event codes or maintain a list that defines the event codes. The limited amount of data that can be displayed at any one time presents additional drawbacks and disadvantages. First, instructions and diagnostics that are displayed to the user when calibrating the system and using the system to obtain a blood glucose reading must be displayed a line at a time and in many cases, the information must be displayed in a cryptic manner. This limitation increases the likelihood that some potential users of the system (particularly children and the elderly) either will find the system complex to use or will not achieve the maximum benefit available from system use.

The above-discussed display limitations and other aspects of currently available blood glucose monitoring systems is disadvantageous in yet another way. Little statistical information can be made available to the user. For example, in diabetic healthcare maintenance, changes or fluctuations that occur in blood glucose levels during a day, a week, or longer period can provide valuable information to a diabetic and/or his or her healthcare professional. As previously mentioned, currently available systems do not allow associating blood glucose test results with attendant quantitative information relating to medication, food intake, or other factors such as exercise that affect a person's blood glucose level at any particular point in time. Thus, currently available blood glucose monitoring systems are not able to generate or display trend information that may be of significant value to a diabetic or the diabetic's healthcare professional.

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The lack of provision for the entering of alphanumeric data also can be a disadvantage. For example, currently available blood glucose monitoring systems do not allow the user or the healthcare professional to enter information into the system such as medication dosage and other instructions or data that is relevant to the user's self-care health program. X

The above-discussed disadvantages and drawbacks of currently available microprocessor-based blood glucose monitoring systems also have been impediments to adopting the basic technology of the system for other healthcare situations in which establishing and maintaining an effective regimen for cure or control is dependent upon (or at least facilitated by) periodically monitoring a condition and recording that condition along with time and date tags and other information necessary or helpful in establishing and maintaining a healthcare program.

#### Summary of the Invention

This invention provides a new and useful system for healthcare maintenance in which the invention serves as a peripheral device to a small handheld microprocessor-based unit of the type that includes a display screen, buttons or keys that allow a user to control the operation of the device and a program cartridge or other arrangement that can be inserted in the device to adapt the device to a particular application or function. The invention in effect converts the handheld microprocessor device into a healthcare monitoring system that has significant advantages over systems such as the currently available blood glucose monitoring systems. To perform this conversion, the invention includes a microprocessor-based healthcare data management unit, a program cartridge and a monitoring unit. When inserted in the handheld microprocessor unit, the program cartridge provides the software necessary to program the handheld microprocessor unit for operation with the microprocessor-based data management unit. Signal

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communication between the data management unit and the handheld microprocessor unit is established by an interface cable. A second interface cable can be used to establish signal communication between the data management unit and the monitoring unit or, alternatively, the monitoring unit can be constructed as a plug-in unit having an electrical connector that mates with a connector mounted within a region that is configured for receiving the monitoring unit.

In operation, the control buttons or keys of the handheld microprocessor-based unit are used to select the operating mode for both the data management unit and the handheld microprocessor-based unit. In response to signals generated by the control buttons or keys, the data management unit generates signals that are coupled to the handheld microprocessor unit and, under control of the software contained in the program cartridge, establish an appropriate screen display on the handheld microprocessor-based unit display. In selecting system operating mode and other operations, the control buttons are used to position a cursor or other indicator in a manner that allows the system user to easily select a desired operating mode or function and provide any other required operator input. In the disclosed detailed embodiment of the invention several modes of operation are made available.

#### Brief Description of the Drawings

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same becomes better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIGURE 1 is a block diagram that illustrates a healthcare monitoring system arranged in accordance with the invention;

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FIGURE 2 diagrammatically illustrates monitoring systems constructed in accordance with the invention connected in signal communication with a remotely located computing facility which includes provision for making the data supplied by the monitoring system of the invention available to a designated healthcare professional and/or for providing data and instructions to the system user;

FIGURE 3 is a block diagram diagrammatically depicting the structural arrangement of the system data management unit and its interconnection with other components of the system shown in FIGURE 1; and

FIGURES 4-10 depict typical system screen displays of data and information that can be provided by the arrangements shown in FIGURES 1-3.

#### Detailed Description

FIGURE 1 depicts a self-care health monitoring system arranged in accordance with the invention. In the arrangement shown in FIGURE 1, a data management unit 10 is electrically interconnected with a handheld microprocessor-based unit 12 via a cable 14. Data management unit 10 also is electrically interconnected with a blood glucose monitor 16 of the type capable of sensing blood glucose level and producing an electrical signal representative thereof. Although FIGURE 1 illustrates blood glucose monitor 16 as being connected to data management unit 10 by a cable 18, it may be preferable to construct blood glucose monitor 16 as a plug-in unit that is placed in a recess or other suitable opening or slot in data management unit 10. Regardless of the manner in which blood glucose monitor 16 is interconnected with data management unit 10, both that interconnection and cable 14 are configured for serial data communication between the interconnected devices.

Also shown in FIGURE 1 are two additional monitoring devices 20 and 22, which are electrically connected for serial data communication with data management unit 10

via cables 24 and 26, respectively. Monitoring units 20 and 22 of FIGURE 1 represent devices other than blood glucose monitor 16 that can be used in the practice of the invention. For example, monitors can be provided for monitoring conditions such as blood pressure, pulse, and body temperature to thereby realize systems for self-care monitoring and control of conditions such as hypertension, certain heart conditions and various other afflictions and physical conditions. As is the case with blood glucose monitor 16, the additional monitors can be configured as plug-in units that are directly received by data management unit 10, or can be connected to data management unit 10 with cables (as shown in FIGURE 1).

As is shown in FIGURE 1, handheld microprocessor unit 12 includes a display screen 28 and a plurality of switches or keys (30, 32, 34, 36, and 38 in FIGURE 1), which are mounted on a small housing 40. Located in the interior of housing 40, but not shown in FIGURE 1, are a microprocessor, memory circuits, and circuitry that interfaces switches 30, 32, 34, 36 and 38 with the microprocessor. Stored in the memory of program handheld microprocessor unit 12 is a set of program instructions that establishes a data protocol that allows handheld microprocessor unit 12 to perform digital data signal processing and generate desired data or graphics for display on display unit 28 when a program cartridge 42 is inserted in a slot or other receptacle in housing 40. That is, program cartridge 42 includes read-only memory units (or other memory means such as battery-powered random access memory) which stores program instructions and data. When combined with program instructions and data included in the internal memory circuits of handheld microprocessor unit 12, the instructions and data of program cartridge 42 cause handheld microprocessor unit 12 to be programmed for a particular purpose or use. As is known in the art, the program instructions and data stored in the internal memory of handheld microprocessor-based unit 12 can be configured and

-10-

arranged so that different program cartridges configure handheld microprocessor unit 12 for different applications or purposes. In each such purpose or application, the plurality of switches or keys (30, 32, 34, 36, and 38 in FIGURE 1) are selectively operated to provide signals that result in pictorial and/or printed information being displayed by display unit 42.

Various devices are known that meet the above-set forth description of handheld microprocessor unit 12. For example, compact devices are available in which the plurality of keys allows alphanumeric entry and internal memory is provided for storing information such as names, addresses, phone numbers, and an appointment calendar. Small program cartridges or cards can be inserted in these devices to program the device for various purposes such as the playing of games, spreadsheet application, and foreign language translation sufficient for use in travel. More recently, less compact products that have more extensive computational capability and are generally called "palm top computers" have been introduced into the marketplace. These devices also can include provision for programming the device by means of an insertable program card or cartridge.

The currently preferred embodiments of the invention are configured and arranged to operate in conjunction with yet another type of handheld microprocessor unit. Specifically, in the currently preferred embodiments of the invention, program cartridge 42 is electrically and physically compatible with commercially available compact video game systems, such as the system manufactured by Nintendo of America Inc. under the trademark "GAME BOY." Configuring data management unit 10 and program cartridge 42 for operation with a handheld video game system has several advantages. For example, the display unit of such a device provides display resolution that allows the invention to display both multi-line alphanumeric information and graphical data. In this

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regard, the 160 x 144 pixel dot matrix-type liquid crystal display screen currently used in the above-referenced compact video game systems provides sufficient resolution for at least six lines of alphanumeric text, as well as allowing graphical representation of statistical data such as graphical representation of blood glucose test results for a day, a week, or longer.

Another advantage of realizing handheld microprocessor unit 12 in the form of a compact video game system is the relatively simple, yet versatile arrangement of switches that is provided by such a device. For example, as is indicated in FIGURE 1, a compact video game system includes a control pad 30 that allows an object displayed on display unit 42 to be moved in a selected direction (i.e., up-down or left-right). As also is indicated in FIGURE 1, compact video game systems typically provide two pair of distinctly-shaped push button switches. In the arrangement shown in FIGURE 1, a pair of spaced-apart circular push button switches (36 and 38) and a pair of elongate switches (32 and 34) are provided. The functions performed by the two pairs of switches is dependent upon the program instructions contained in each program cartridge 42.

Yet another advantage of utilizing a compact video game system for handheld microprocessor based unit 12 of FIGURE 1 is the widespread popularity and low cost of such units. In this regard, manufacture and sale of a data management unit 10, blood glucose monitor 16 and program cartridge 42 that operate in conjunction with a compact microprocessor based video allows the self-care health monitoring system of FIGURE 1 to be manufactured and sold at a lower cost than could be realized in an arrangement in which handheld unit 12 is designed and manufactured solely for use in the system of FIGURE 1.

An even further advantage of using a compact video game system for handheld microprocessor 12 is that such video game systems include means for easily establishing

the electrical interconnection provided by cable 14 in FIGURE 1. In particular, such compact video game systems include a connector mounted to the game unit housing (40 in FIGURE 1) and a cable that can be connected between the connectors of two video game units to allow interactive operation of the two interconnected units (i.e., to allow contemporaneous game play by two players or competition between players as they individually play identical but separate games). In the preferred embodiments of the invention, the "two-player" cable supplied with the compact video game unit being used as handheld microprocessor unit 12 is used as cable 14 to establish serial data communication between the handheld microprocessor unit 12 (compact video game system) and data management unit 10. In these preferred embodiments, the program instructions stored on the memory of data management unit 10 and program cartridge 42 respectively program data management unit 10 and the compact video game system (i.e., handheld microprocessor unit 12) for interactive operation in which switches 30, 32, 34, 36 and 38 are used to control the operation of data management unit 10 (e.g., to select a particular operational mode such as performance of a blood glucose test or the display of statistical test data and, in addition, to control operation such as selection of an option during operation of the system in a particular operational mode). In each operational mode, data management unit 10 processes data in accordance with program instructions stored in the memory circuits of data management unit 10. Depending upon the operational mode selected by the user, data is supplied to data management unit 10 by blood glucose monitor 16, by additional monitors (20 and 22 in FIGURE 1) or any interconnected computers (hereinafter described as elements 48 and 54 in FIGURE 1). During operational mode, switches 30, 32, 34, 36 and 38 are selectively activated so that signals are selectively coupled to the video game system (handheld microprocessor unit 12) and processed in accordance with program instructions stored in program



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cartridge 42. The signal processing performed by handheld microprocessor unit 12 results in the display of alphanumeric, symbolic, or graphic information on the video game display screen (i.e., display unit 28 in FIGURE 1) which allow the user to control system operation and obtain desired test results and other information.

With continued reference to FIGURE 1, data management unit 10 of the currently preferred embodiments of the invention includes a data port 44 that allows communication between data management unit 10 and a personal computer 48 (or other programmable data processor). In the currently preferred embodiments of the invention, data port 44 is an RS-232 connection that allows serial data communication between data management unit 10 and personal computer 48. In the practice of the invention, personal computer 48 can be used to supplement data management unit 10 by, for example, performing relatively complex or sophisticated analyses of blood glucose and other data that has been supplied to and stored in the memory circuits of data management unit 10. Alternatively, personal computer 48 can be used to supply data to data management unit 10 that is not conveniently supplied by using handheld microprocessor switches 30, 32, 34, 36 and 38 as an operator interface to the system shown in FIGURE 1. For example, some embodiments of the invention may employ a substantial amount of alphanumeric information that must be entered by the system user. Although it is possible to enter such data by using switches 30, 32, 34, 36 and 38 in conjunction with menus and selection screens displayed on display screen 28 of FIGURE 1, it may be more advantageous to use a device such as personal computer 48 for entry of such data. However, if personal computer 48 is used in this manner, some trade-off of system features may be required because data management unit 10 must be temporarily interconnected with personal computer 48 during these operations. That is, some loss of

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system mobility might result because a suitably programmed personal computer would be needed at each location at which data entry or analysis is to occur.

As is indicated in FIGURE 1, data management unit 10 of the currently preferred embodiments of the invention also includes a modem that allows data communication between data management unit 10 and a remote computing facility 54 via a conventional telephone line (indicated by reference numeral 50 in FIGURE 1) and a modem 52 that interconnects remote computing facility 54 and telephone line 50. As shall be described in more detail, remote computing facility 54 facilitates communication between a user of the system shown in FIGURE 1 and his or her healthcare professional and can provide additional services such as updating system software.

Regardless of whether a compact video game system, another type of commercially available handheld microprocessor-based unit, or a specially designed unit is used, the preferred embodiments of FIGURE 1 provide a self-care blood glucose monitoring system in which program cartridge 42: (a) adapts handheld microprocessor unit 12 for displaying instructions for performing the blood glucose test sequence and associated calibration and test procedures; (b) adapts handheld microprocessor unit 12 for displaying (graphically or alphanumerically) statistical data such as blood glucose test results taken during a specific period of time (e.g., a day, week, etc.); (c) adapts handheld microprocessor unit 12 for supplying control signals and signals representative of food intake or other useful information to data management unit 10; (d) adapts handheld microprocessor unit 12 for simultaneous graphical display of blood glucose levels with information such as food intake; and, (e) adapts handheld microprocessor unit 12 for displaying information or instructions from a healthcare professional that are coupled to data management unit 10 from a remote computing facility 54. The manner in which the

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arrangement of FIGURE 1 implements the above-mentioned functions and others can be better understood with reference to FIGURES 2 and 3.

Referring first to FIGURE 2, in relatively large scale application of the invention, remote computing facility 54 of FIGURE 1 functions as a clearinghouse (i.e., central server) that is identified by reference numeral 56 in FIGURE 2. Clearinghouse 56 receives data from a plurality of self-care microprocessor-based healthcare systems of the type shown in FIGURE 1, with the individual self-care health monitoring systems being indicated in FIGURE 2 by reference numeral 58. Preferably, the data supplied to clearinghouse 56 by each individual self-care health monitoring system 58 consists of "raw data," i.e., test results and related data that was stored in memory circuits of data management unit 10, without further processing by data management unit 10. For example, with respect to the arrangement shown in FIGURE 1, blood glucose test results and associated data such as food intake information, medication dosage and other such conditions are transmitted to clearinghouse 56 and stored with a digitally encoded signal that identifies both the source of the information (i.e., the system user or patient) and those having access to the stored information (i.e., the system user's doctor or other healthcare professional).

In FIGURE 2, rectangular outline 60 represents one of numerous remotely located healthcare professionals who can utilize clearinghouse 56 and the arrangement described relative to FIGURE 1 in monitoring and controlling patient healthcare programs. Shown within outline 60 is a computer 62 (e.g., personal computer), which is coupled to clearinghouse 56 by means of a modem (not shown in FIGURE 2) and a telephone line 64. The arrangement of FIGURE 2 also diagrammatically indicates a facsimile machine ("fax"), which is coupled to clearinghouse 56 by means of a second

device such as a mouse), the healthcare professional can establish data communication between computer 62 and clearinghouse 56 via telephone line 64. Once data communication is established between computer 62 and clearinghouse 56, patient information can be obtained from clearinghouse 56 in a manner similar to the manner in which subscribers to various database services access and obtain information. In particular, the healthcare professional can transmit an authorization code to clearinghouse 56 that identifies the healthcare professional as an authorized user of the clearinghouse and, in addition, can transmit a signal representing the patient for which healthcare information is being sought. As is the case with conventional database services and other arrangements, the identifying data is keyed into computer 62 by means of a conventional keyboard (not shown in FIGURE 2) in response to prompts that are generated at clearinghouse 56 for display by the display unit of computer 62 (not shown in FIGURE 2).

Depending upon the hardware and software arrangement of clearinghouse 56 and selections made by the healthcare professional via computer 62, patient information can be provided to the healthcare professional in different ways. For example, computer 62 can be operated to access data in the form that it is stored in the memory circuits of clearinghouse 56 (i.e., raw data that has not been processed or altered by the computational or data processing arrangements of clearinghouse 56). Such data can be processed, analyzed, printed and/or displayed by computer 62 using commercially available or custom software. On the other hand, various types of analyses may be performed by clearinghouse 56 with the results of the analyses being transmitted to the remotely located healthcare professional 60. For example, clearinghouse 56 can process and analyze data in a manner identical to the processing and analysis provided by the self-care monitoring system of FIGURE 1. With respect to such processing and any other

analysis and processing provided by clearinghouse 56, results expressed in alphanumeric format can be sent to computer 62 via telephone line 64 and the modem associated with computer 62, with conventional techniques being used for displaying and/or printing the alphanumeric material for subsequent reference. In addition, the arrangement of FIGURE 2 allows analytical or statistical results to be transmitted to remotely located healthcare professional 60 via telephone line 68 and facsimile machine 66. For example, data supplied by the arrangement can be processed by clearinghouse 56 using conventional data processing techniques to obtain a collection of data or statistical information that lends itself to presentation in a pictorial or graphic format. In such a case, the data can be converted by clearinghouse 56 to a conventional facsimile transmission format, which can be sent to the healthcare professional's facsimile machine 66 upon request of the healthcare professional (i.e., communication via computer 62).

The arrangement of FIGURE 2 also allows the healthcare professional to send messages and/or instructions to each patient via computer 62, telephone line 64, and clearinghouse 56. In particular, clearinghouse 56 can be programmed to generate a menu that is displayed by computer 62 and allows the healthcare professional to select a mode of operation in which information is to be sent to clearinghouse 56 for subsequent transmission to a user of the system described relative to FIGURE 1. This same menu (or related submenus) can be used by the healthcare professional to select one or more modes of operation of the above-described type in which either unmodified patient data or the results of data that has been analyzed by clearinghouse 56 is provided to the healthcare provider via computer 62 and/or facsimile machine 66.

In the currently contemplated arrangements, operation of the arrangement of FIGURE 2 to provide the user of the invention with messages or instructions such as

changes in medication or other aspects of the healthcare program is similar to the operation that allows the healthcare professional to access data sent by a patient, i.e., transmitted to clearinghouse 56 by a data management unit 10 of FIGURE 1. The process differs in that the healthcare professional enters the desired message or instruction via the keyboard or other interface unit of computer 62. Once the data is entered and transmitted to clearinghouse 56, it is stored for subsequent transmission to the user for whom the information or instruction is intended.

With respect to transmitting stored messages or instructions to a user of the invention, at least two techniques are available. The first technique is based upon the manner in which operational modes are selected in the practice of the invention. Specifically, in the currently preferred embodiments of the invention, program instructions that are stored in data management unit 10 and program cartridge 42 cause the system of FIGURE 1 to generate menu screens which are displayed by display unit 28 of handheld microprocessor unit 12. The menu screens allow the system user to select the basic mode in which the system of FIGURE 1 is to operate and, in addition, allow the user to select operational subcategories within the selected mode of operation. Various techniques are known to those skilled in the art for displaying and selecting menu items. For example, in the practice of this invention, one or more main menus can be generated and displayed which allow the system user to select operational modes that may include: (a) a monitor mode (e.g., monitoring of blood glucose level); (b) a display mode (e.g., displaying previously obtained blood glucose test results or other relevant information); (c) an input mode (e.g., a mode for entering data such as providing information that relates to the healthcare regimen, medication dosage, food intake, etc., and (d) a communications mode (for establishing a communication link between data management

unit 10 and personal computer 48 of FIGURE 1; or between data management Unit 10 and a remote computing facility such as clearinghouse 56 of FIGURE 2).

In embodiments of the invention that employ a compact video game system for handheld microprocessor unit 12, the selection of menu screens and the selection of menu screen items preferably is accomplished in substantially the same manner as menu screens and menu items are selected during the playing of a video game. For example, the program instructions stored in data management unit 10 and program cartridge 42 of the arrangement of FIGURE 1 can be established so that a predetermined one of the compact video game switches (e.g., switch 32 in FIGURE 1) allows the system user to select a desired main menu in the event that multiple main menus are employed. When the desired main menu is displayed, operation by the user of control pad 30 allows a cursor or other indicator that is displayed on the menu to be positioned adjacent to or over the menu item to be selected. Activation of a switch (e.g., switch 36 of the depicted handheld microprocessor unit 12) causes the handheld microprocessor unit 12 and/or data management unit 10 to initiate the selected operational mode or, if selection of operational submodes is required, causes handheld microprocessor unit 12 to display a submenu.

In view of the above-described manner in which menus and submenus are selected and displayed, it can be recognized that the arrangement of FIGURE 1 can be configured and arranged to display a menu or submenu item that allows the user to obtain and display messages or instructions that have been provided by a healthcare professional and stored in clearinghouse 56. For example, a submenu that is generated upon selection of the previously mentioned communications mode can include submenu items that allow the user to select various communication modes, including a mode in which serial data communication is established between data management unit 10 and clearinghouse 56 and

data management unit 10 transmits a message status request to clearinghouse 56. When this technique is used, the data processing system of clearinghouse 56 is programmed to search the clearinghouse memory to determine whether a message exists for the user making the request. Any messages stored in memory for that user are then transmitted to the user and processed for display on display unit 28 of handheld microprocessor unit 12. If no messages exist, clearinghouse 56 transmits a signal that causes display unit 28 to indicate "no messages." In this arrangement, clearinghouse 56 preferably is programmed to store a signal indicating that a stored message has been transmitted to the intended recipient (user). Storing such a signal allows the healthcare professional to determine that messages sent to clearinghouse 56 for forwarding to a patient have been transmitted to that patient. In addition, the program instructions stored in data management unit 10 of FIGURE 1 preferably allow the system user to designate whether received messages and instructions are to be stored in the memory of data management unit 10 for subsequent retrieval or review. In addition, in some instances it may be desirable to program clearinghouse 56 and data management unit 10 so that the healthcare professional can designate (i.e., flag) information such as changes in medication that will be prominently displayed to the user (e.g., accompanied by a blinking indicator) and stored in the memory of data management unit 10 regardless of whether the system user designates the information for storage.

A second technique that can be used for forwarding messages or instructions to a user does not require the system user to select a menu item requesting transmission by clearinghouse 56 of messages that have been stored for forwarding to that user. In particular, clearinghouse 56 can be programmed to operate in a manner that either automatically transmits stored messages for that user when the user operates the system of FIGURE 1 to send information to the clearinghouse or programmed to operate in a



manner that informs the user that messages are available and allows the user to access the messages when he or she chooses to do so.

FIGURE 3 illustrates the manner in which data management unit 10 is arranged and interconnected with other system components for effecting the above-described operational aspects of the invention and additional aspects that are described relative to FIGURES 4-10. As is symbolically indicated in FIGURE 3, handheld microprocessor unit 12 and blood glucose monitor 16 are connected to a dual universal asynchronous receiver transmitter 70 (e.g., by cables 14 and 18 of FIGURE 1, respectively). As also is indicated in FIGURE 3 when a personal computer 48 (or other programmable digital signal processor) is connected to data port 44 signal communication is established between personal computer 48 and a second dual universal asynchronous receiver transmitter 72, which is included in data management unit 10. Additionally, dual universal asynchronous receiver transmitter 72 is coupled to modem 46 so that data communication can be established between data management unit 10 and a remote computing facility 54 (e.g., clearinghouse 56 of FIGURE 2).

Currently preferred embodiments of data management unit 10 include a plurality of signal sensors 74, with an individual signal sensor being associated with each device that is (or may be) interconnected with data management unit 10. As previously discussed and as is indicated in FIGURE 3, these devices include handheld microprocessor unit 12, blood glucose monitor 16, personal computer 48, and remote computing facility 54. Each signal sensor 74 that is included in data management unit 10 is electrically connected for receiving a signal that will be present when the device with which that particular signal sensor is associated is connected to data management unit 10 and, in addition, is energized (e.g., turned on). For example, in previously mentioned embodiments of the invention in which data port 44 is an RS-232 connection, the signal

sensor 74 that is associated with personal computer 48 can be connected to an RS-232 terminal that is supplied power when a personal computer is connected to data port 44 and the personal computer is turned on. In a similar manner, the signal sensor 74 that is associated with remote computing facility 54 can be connected to modem 46 so that the signal sensor 74 receives an electrical signal when modem 46 is interconnected to a remote computing facility (e.g., clearinghouse 56 of FIGURE 2) via a telephone line 50.

In the arrangement of FIGURE 3, each signal sensor 74 is a low power switch circuit (e.g., a metal-oxide semiconductor field-effect transistor circuit), which automatically energizes data management unit 10 whenever one or more of the devices associated with signal sensors 74 are connected to data management unit 10 and are energized. Thus, as is indicated in FIGURE 3 by signal path 76, each signal sensor 74 is interconnected with power supply 78, which supplies operating current to the circuitry of data management unit 10 and typically consists of one or more small batteries (e.g., three AAA alkaline cells).

The microprocessor and other conventional circuitry that enables data management unit 10 to process system signals in accordance with stored program instructions is indicated in FIGURE 3 by central processing unit (CPU) 80. As is indicated in FIGURE 3 by interconnection 82 between CPU 80 and battery 78, CPU 80 receives operating current from power supply 78, with power being provided only when one or more of the signal sensors 74 are activated in the previously described manner. A clock/calendar circuit 84 is connected to CPU 80 (via signal path 86 in FIGURE 3) to allow time and date tagging of blood glucose tests and other information. Although not specifically shown in FIGURE 3, operating power is supplied to clock/calendar 84 at all times.

In operation, CPU 80 receives and sends signals via a data bus (indicated by signal path 88 in FIGURE 3) which interconnects CPU 80 with dual universal asynchronous receiver transmitters 70 and 72. The data bus 88 also interconnects CPU 80 with memory circuits which, in the depicted embodiment, include a system read-only memory (ROM) 90, a program random access memory (RAM) 92, and an electronically erasable read-only memory (EEROM) 94. System ROM 90 stores program instructions and any data required in order to program data management unit 10 so that data management unit 10 and a handheld microprocessor unit 12 that is programmed with a suitable program cartridge 72 provide the previously discussed system operation and system operation that will be described relative to FIGURES 4-10. During operation of the system, program RAM 92 provides memory space that allows CPU 80 to carry out various operations that are required for sequencing and controlling the operation of the system of FIGURE 1. In addition, RAM 92 can provide memory space that allows external programs (e.g., programs provided by clearinghouse 56) to be stored and executed. EEROM 94 allows blood glucose test results and other data information to be stored and preserved until the information is no longer needed (i.e., until purposely erased by operating the system to provide an appropriate erase signal to EEROM 94).

FIGURES 4-10 illustrate typical screen displays that are generated by the arrangement of the invention described relative to FIGURES 1-3. Reference will first be made to FIGURES 4 and 5, which exemplify screen displays that are associated with operation of the invention in the blood glucose monitoring mode. Specifically, in the currently preferred embodiments of the invention, blood glucose monitor 16 operates in conjunction with data management unit 10 and handheld microprocessor unit 12 to:

- (a) perform a test or calibration sequence in which tests are performed to confirm that the system is operating properly; and,
- (b) perform the blood glucose test sequence in which

blood glucose meter 16 senses the user's blood glucose level. Suitable calibration procedures for blood glucose monitors are known in the art. For example, blood glucose monitors often are supplied with a "code strip," that is inserted in the monitor and results in a predetermined value being displayed and stored in memory at the conclusion of the code strip calibration procedure. When such a code strip calibration procedure is used in the practice of the invention, the procedure is selected from one of the system menus. For example, if the system main menu includes a "monitor" menu item, a submenu displaying system calibration options and an option for initiating the blood glucose test may be displayed when the monitor menu item is selected. When a code strip option is available and selected, a sequence of instructions is generated and displayed by display screen 28 of handheld microprocessor unit 12 to prompt the user to insert the code strip and perform all other required operations. At the conclusion of the code strip calibration sequence, display unit 28 of handheld microprocessor unit 12 displays a message indicating whether or not the calibration procedure has been successfully completed. For example, FIGURE 4 illustrates a screen display that informs the system user that the calibration procedure was not successful and that the code strip should be inserted again (i.e., the calibration procedure is to be repeated). As is indicated in FIGURE 4, display screens that indicate a potential malfunction of the system include a prominent message such as the "Attention" notation included in the screen display of FIGURE 4.

As previously indicated, the blood glucose test sequence that is employed in the currently preferred embodiment of the invention is of the type in which a test strip is inserted in a receptacle that is formed in the blood glucose monitor. A drop of the user's blood is then applied to the test strip and a blood glucose sensing sequence is initiated. When the blood glucose sensing sequence is complete, the user's blood glucose level is displayed.

In the practice of the invention, program instructions stored in data management unit 10 (e.g., system ROM 90 of FIGURE 3) and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 cause the system to display step-by-step monitoring instructions to the system user and, in addition, preferably result in display of diagnostic messages if the test sequence does not proceed in a normal fashion. Although currently available self-contained microprocessor base blood glucose monitors also display test instruction and diagnostic messages, the invention provides greater message capacity and allows multi-line instructions and diagnostic messages that are displayed in easily understood language rather than cryptic error codes and abbreviated phraseology that is displayed one line at a time. For example, as is shown in FIGURE 5, the complete results of a blood glucose test (date, time of day, and blood glucose level in milligrams per deciliter) can be concurrently displayed by display screen 28 of handheld microprocessor unit 12 along with an instruction to remove the test strip from blood glucose monitor 16. As previously mentioned, when the blood glucose test is complete, the time and date tagged blood glucose test result is stored in the memory circuits of data management unit 10 (e.g., stored in EEPROM 94 of FIGURE 3).

The arrangement shown and described relative to FIGURES 1-3 also is advantageous in that data relating to food intake, concurrent medication dosage and other conditions easily can be entered into the system and stored with the time and date tagged blood glucose test result for later review and analysis by the user and/or his or her healthcare professional. Specifically, a menu generated by the system at the beginning or end of the blood glucose monitoring sequence can include items such as "hypoglycemic" and "hyperglycemic," which can be selected using the switches of handheld microprocessor unit 12 (e.g., operation of control pad 30 and switch 36 in FIGURE 1) to indicate the user was experiencing hypoglycemic or hyperglycemic symptoms at the time

of monitoring blood glucose level. Food intake can be entered in terms of "Bread Exchange" units or other suitable terms by selecting a "food intake menu item and using a submenu display and the switches of handheld microprocessor 12 to select and enter the appropriate information. A similar menu item - submenu selection process also can be used to enter medication data such as the type of insulin used at the time of the glucose monitoring sequence and the dosage.

As was previously mentioned, program instructions stored in data management unit 10 and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 enable the system to display statistical and trend information either in a graphic or alphanumeric format. As is the case relative to controlling other operational aspects of the system, menu screens are provided that allow the system user to select the information that is to be displayed. For example, in the previously discussed embodiments in which a system menu includes a "display" menu item, selection of the menu item results in the display of one or more submenus that list available display options. For example, in the currently preferred embodiments, the user can select graphic display of blood glucose test results over a specific period of time, such as one day, or a particular week. Such selection results in displays of the type shown in FIGURES 6 and 7, respectively. When blood glucose test results for a single day are displayed (FIGURE 6), the day of the week and date can be displayed along with a graphic representation of changes in blood glucose level between the times at which test results were obtained. In the display of FIGURE 6, small icons identify points on the graphic representation that correspond to the blood glucose test results (actual samples). Although not shown in FIGURE 6, coordinate values for blood glucose level and time of day can be displayed if desired. When the user chooses to display a weekly trend graph (FIGURE 7), the display generated by the system is similar to the display of a daily graph,

having the time period displayed in conjunction with a graph that consists of lines interconnecting points that correspond to the blood glucose test results.

The screen display shown in FIGURE 8 is representative of statistical data that can be determined by the system of FIGURE 1 (using conventional computation techniques) and displayed in alphanumeric format. More specifically, the exemplary screen display of FIGURE 8 provides statistical data for blood glucose levels over a period of time (e.g., one week) or, alternatively, for a specified number of monitoring tests. In the exemplary display of FIGURE 8, the system calculates and displays the average blood glucose level and the standard deviation. Displayed also is the number of blood glucose test results that were analyzed to obtain the average and the standard deviation; the number of test results under a predetermined level (50 milligrams per deciliter in the screen display shown in FIGURE 8); and the number of blood glucose tests that were conducted while the user was experiencing hypoglycemic symptoms. As previously noted, in the preferred embodiments of the invention, a screen display that is generated during the blood glucose monitoring sequence allows the user to identify the blood sample being tested as one taken while experiencing hyperglycemic or hypoglycemic symptoms and, in addition, allows the user to specify other relevant information such as food intake and medication information.

The currently preferred embodiments of the invention also allow the user to select a display menu item that enables the user to sequentially address, in chronological order, the record of each blood glucose test. As is indicated in FIGURE 9, each record presented to the system user includes the data and time at which the test was conducted, the blood glucose level, and any other information that the user provided. For example, the screen display of FIGURE 9 indicates that the user employed handheld microprocessor unit 12 as an interface to enter data indicating use of 12.5 units of regular

insulin; 13.2 units of "NPH" insulin; food intake of one bread exchange unit; and pre-meal hypoglycemic symptoms.

Use of data management unit 10 in conjunction with handheld microprocessor unit 12 also allows display of blood glucose test results along with food intake and/or medication information. For example, shown in FIGURE 10 is a daily graph in which blood glucose level is displayed in the manner described relative to FIGURE 6. Related food intake and medication dosage is indicated directly below contemporaneous blood glucose levels by vertical bar graphs.

It will be recognized by those skilled in the art that the above-described screen displays and system operation can readily be attained with conventional programming techniques of the type typically used in programming microprocessor arrangements. It also will be recognized by those skilled in the art that various other types of screen displays can be generated and, in addition, that numerous other changes can be made in the embodiments described herein without departing from the scope and the spirit of the invention.



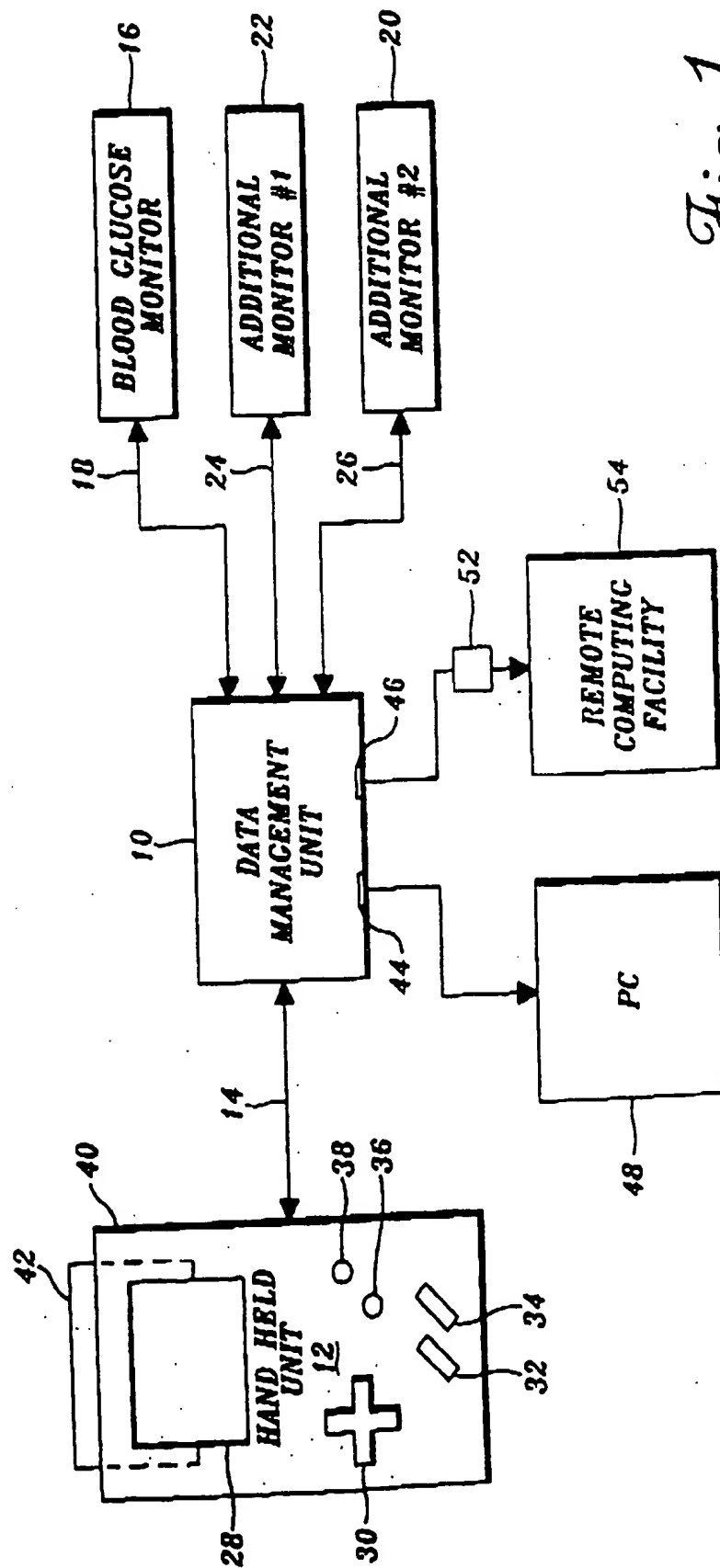


Fig. 1.

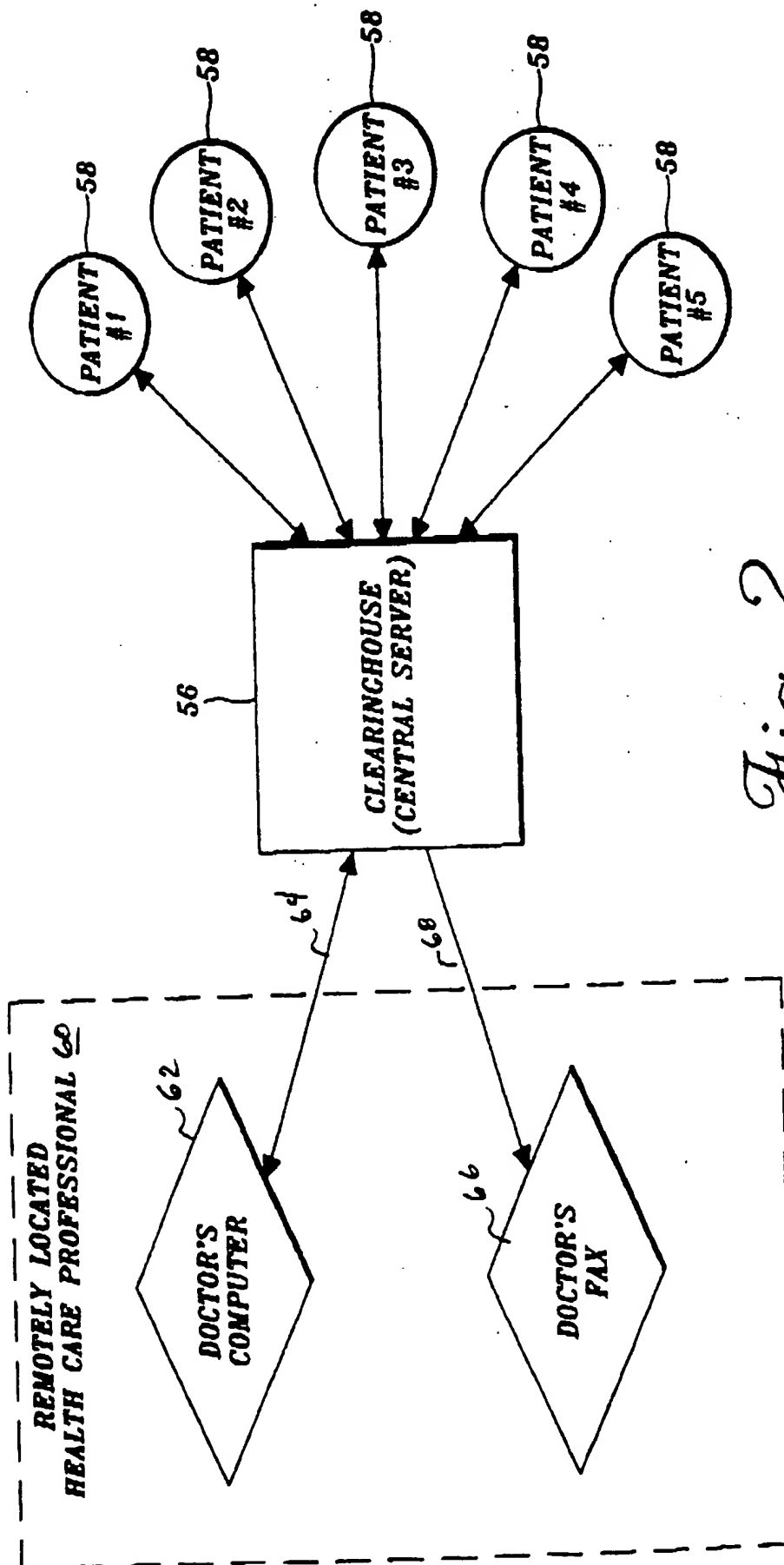
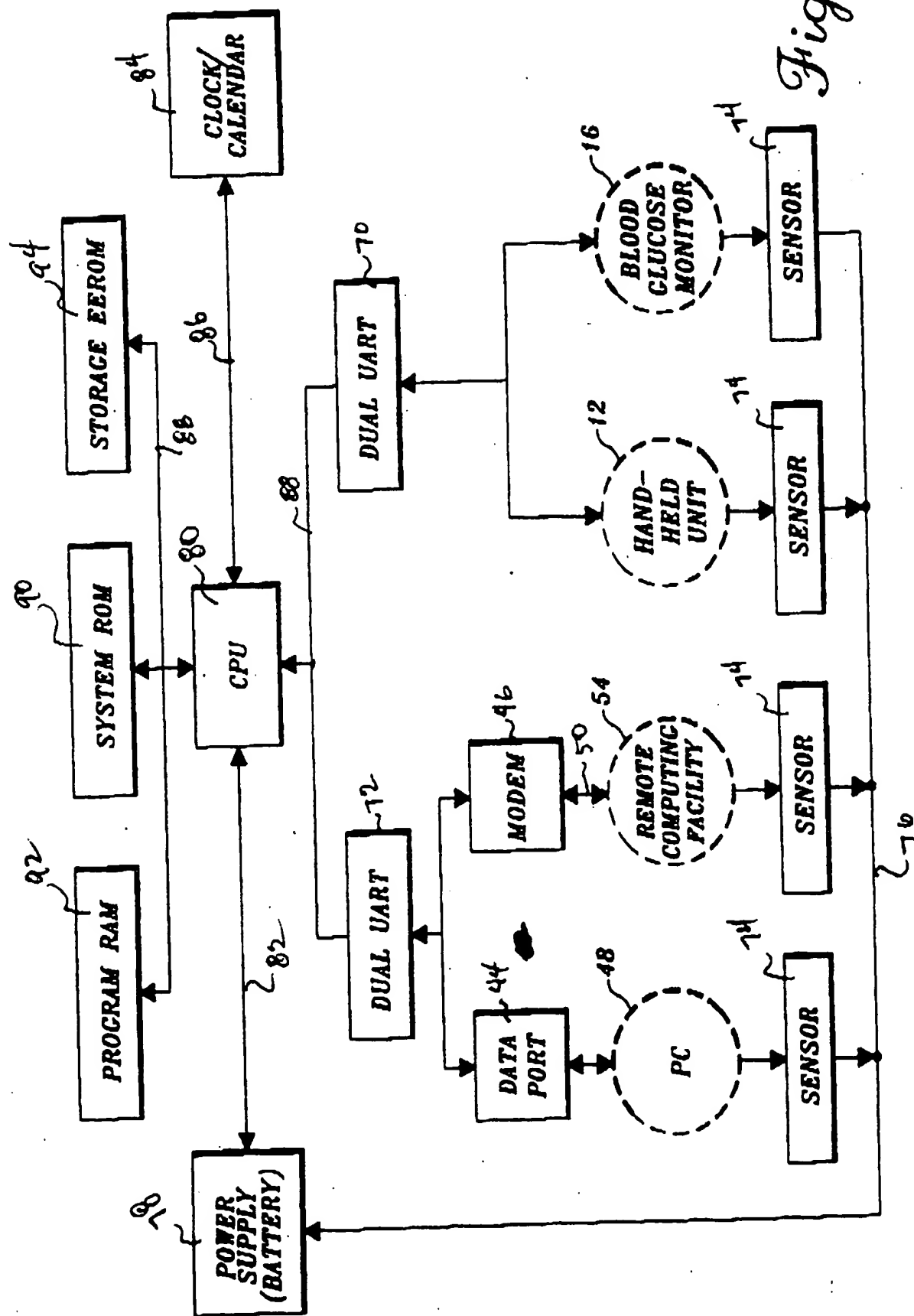
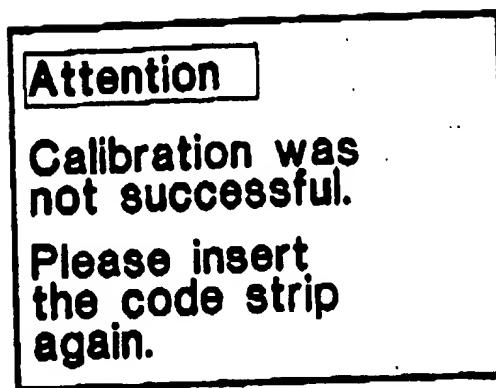


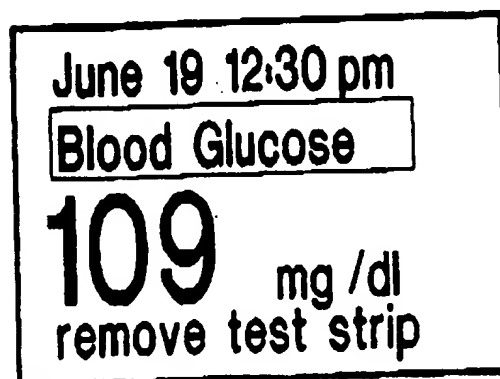
Fig. 2.



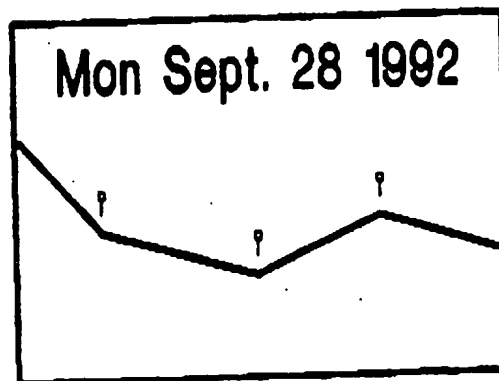
*Fig.4.*



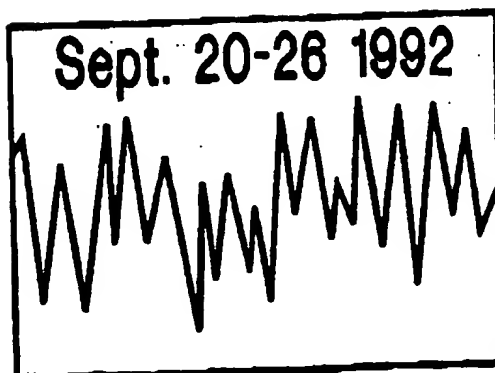
*Fig.5.*



*Fig.6.*



*Fig.7.*



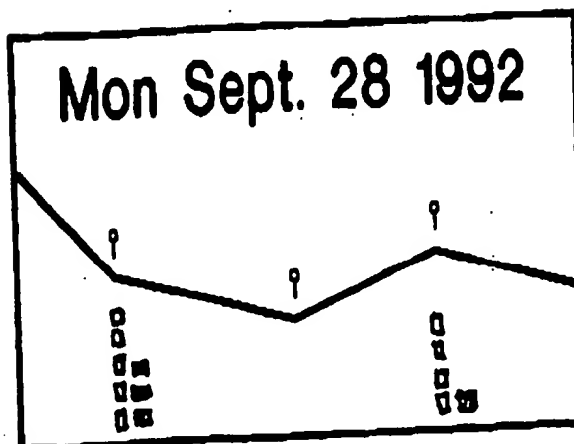
*Fig. 8.*

Glucose  
Ave: 123 mg/dl  
SD: 56  
Num: 15  
No. under 50: 13  
No. hypo sym: 23

*Fig. 9.*

June 12 9:30pm  
BG 113 mg/dl  
Regin 12.5 U  
NPHin 13.2 U  
Food 1 BE  
Pre-meal HYPO

*Fig. 10.*



# Facsimile Cover Sheet

**To:** Mr. James Anable Esq.  
**Company:** Christiansen O'Connor  
**Phone:** (206) 682-8100  
**Fax:** (206) 224-0779

**From:** Steve Brown  
**Company:** Raya Systems, Inc  
**Phone:** (415) 949-3933  
**Fax:** (415) 949-3935

*healthboy*

**Date:** 10/02/92  
**Pages including this  
cover page:** 3

**Comments:**

\*\*\*\*\* PANAFAX 155 \*\*\* -JOURNAL- \*\*\*\*\* DATE 01/17/1900 \*\*\*\*\* TIME 16:07 \*\*\*\*\*

NO.	COM	DOC	DURATION	X/R	IDENTIFICATION	DATE	TIME	DIAGNOSTIC
28	OK	03	00:01:35	XMT	GROUP3	01/17	16:05	020440AC0800

\*\*\*\*\* -PANASONIC- \*\*\*\*\*

- \*\*\*\*\*

October 2, 1992

Mr. James Anable Esq.  
Christiansen O'Connor  
2800 Pacific First Center  
1420 Fifth Avenue  
Seattle, WA 98101

Dear James:

I am faxing you the diagram which shows the basic system. I am worried about focusing on the particulars and losing the fundamentals, and I think this diagram needs to be in the application.

Sincerely,



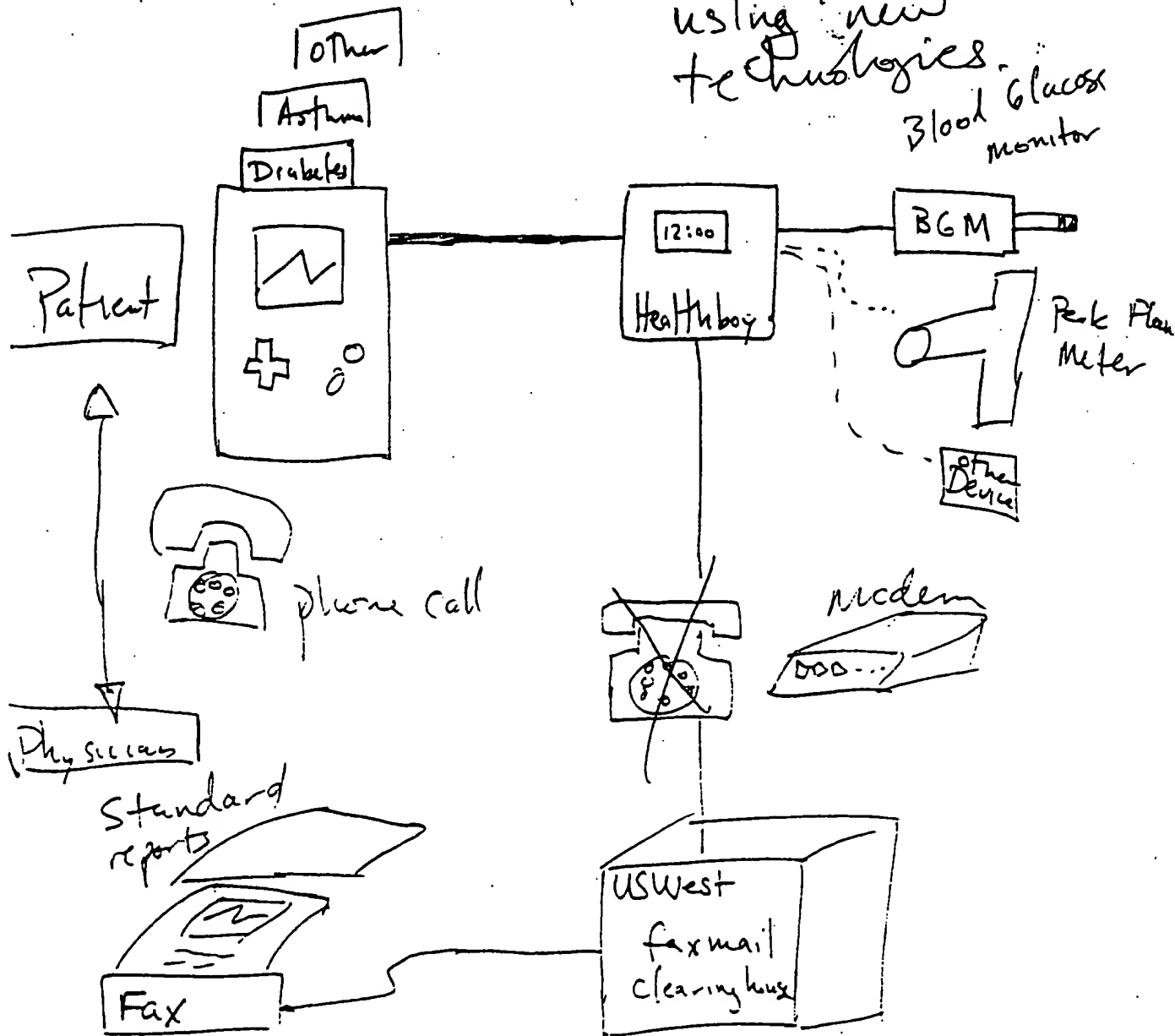
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PAGE 2

Invoice # 632084

For Services And Disbursements

\*\*\*\*\* RAYA-6631  
1>MODULAR MICROPROCESSOR...  
US PATENT APP

Services

OCT 01 92 JWA	Work on patent application	6.80	1,496.00
OCT 02 92 JWA	Review S. Brown comments regarding patent application draft; Review and revise patent application	1.40	308.00
OCT 07 92 JWA	Meeting with S. Brown; Work on patent application	4.90	1,078.00
OCT 27 92 JWA	Review and revise patent application	2.30	506.00
OCT 28 92 JWA	Review and revise patent application	1.50	330.00
OCT 29 92 JWA	Review and revise patent application	1.50	330.00
OCT 29 92 JM	Work on patent drawings	1.30	65.00
	Total Hours	19.70	
	Total Fees		4,113.00

Disbursements

OCT 19 92 FIRM	Telecopier handling charge	2.00
	Photocopies	9.30
	Long distance telephone charges	6.96
	Total Disbursements	18.26

Inable James W	JWA	PTNR	18.40	220.00	4,048.00
lez Joel	JM	ILLU	1.30	50.00	65.00
		ILLU	1.30	50.00	65.00
		PTNR	18.40	220.00	4,048.00

Disbursements

Continued

CHRISTENSEN, O'CONNOR,  
JOHNSON & KINDNESS  
2800 Pacific First Centre  
1420 Fifth Avenue  
Seattle, WA 98101  
(206) 682-8100

RAYA SYSTEMS, INC.

NOVEMBER 30 1992

2570 WEST EL CAMINO REAL  
SUITE 309  
MT. VIEW, CA 94040

PAGE 2

Invoice # 636008

For Services And Disbursements

\*\*\*\*\* RAYA-6631  
1>MODULAR MICROPROCESSOR...  
US PATENT APP SN 977,323 11/17/92  
BROWN SJ

Services

NOV 05 92 JM	Work on patent drawings	.40	20.00
NOV 17 92 JM	Work on patent drawings	.60	51.00
	Total Hours	1.00	
	Total Fees		71.00

Disbursements

NOV 11 92 FIRM	Telecopier handling charge	5.00	
	Long distance telephone charges	.47	
	Total Disbursements		5.47

le z Joel	JM	ILLU	1.00	71.00	71.00
		ILLU	1.00	71.00	71.00

Disbursements

	Long distance telephone charges	.47	
	Telecopier handling charge	5.00	
	Total Hours	1.00	
	Total Fees		71.00
	Total Disbursements		5.47

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\$76.47

Invoice due upon receipt. Interest charged at 1.50% per month from  
invoice date on amounts unpaid 45 days after invoice date.

Christensen, O'Connor, Johnson & Kindness--Tax I.D. No. 91-0860813  
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EXHIBIT AB  
PAGE 1 OF 1

SERIAL NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
07/977,323	11/17/92	2311	\$ 420.00	RAYA-1-6631	5	12	1

CHRISTENSEN, O'CONNOR,  
JOHNSON & KINDNESS  
2800 PACIFIC FIRST CENTRE  
1420 FIFTH AVE.  
SEATTLE, WA 98101

Receipt is acknowledged of the patent application identified herein. It will be considered in its order and you will be notified as to the examination thereof. Be sure to give the U.S. SERIAL NUMBER, DATE OF FILING, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this transmittal.

Applicant(s)                      STEPHEN J. BROWN, PALO ALTO, CA.

FOREIGN FILING LICENSE GRANTED 03/11/93

\* SMALL ENTITY \*

TITLE

MODULAR MICROPROCESSOR-BASED HEALTH MONITORING SYSTEM

PRELIMINARY CLASS: 364

RECEIVED  
MAR 22 1993  
Christensen, O'Connor  
Johnson & Kindness

(see reverse)

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